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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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	:	Examiner: William H. Matthews
IAN M. PENN, ET AL.	)	
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Appln. No. 10/849,990	)	
	:	Confirmation No.: 8691
Filed: May 21, 2004	)	
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For: EXPANDABLE STENT AND METHOD FOR DELIVERY OF SAME	)	August 21, 2006
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	)	

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

MISCELLANEOUS INCOMING LETTER-

SUBMISSION OF DOCUMENTS UNDER 37 CFR § 1.97(i)

Sir:

In accordance with 37 CFR § 1.97(i), please place the attached documents in the subject application file.

Applicants' undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should continue to be directed to our address as given below.

Respectfully submitted,

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United States Patent [19]

Alt et al.

[11] Patent Number: 5,843,117

[45] Date of Patent: Dec. 1, 1998

[54] **IMPLANTABLE VASCULAR AND ENDOLUMINAL STENTS AND PROCESS OF FABRICATING THE SAME**

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[73] Assignee: **Inflow Dynamics Inc.**, Del.

[21] Appl. No.: **599,880**

[22] Filed: **Feb. 14, 1996**

[51] **Int. Cl.**[6] **A61M 29/00**

[52] **U.S. Cl.** **606/194**; 623/1; 623/12; 623/901

[58] **Field of Search** 606/108, 198, 606/191, 195; 623/1, 12, 901

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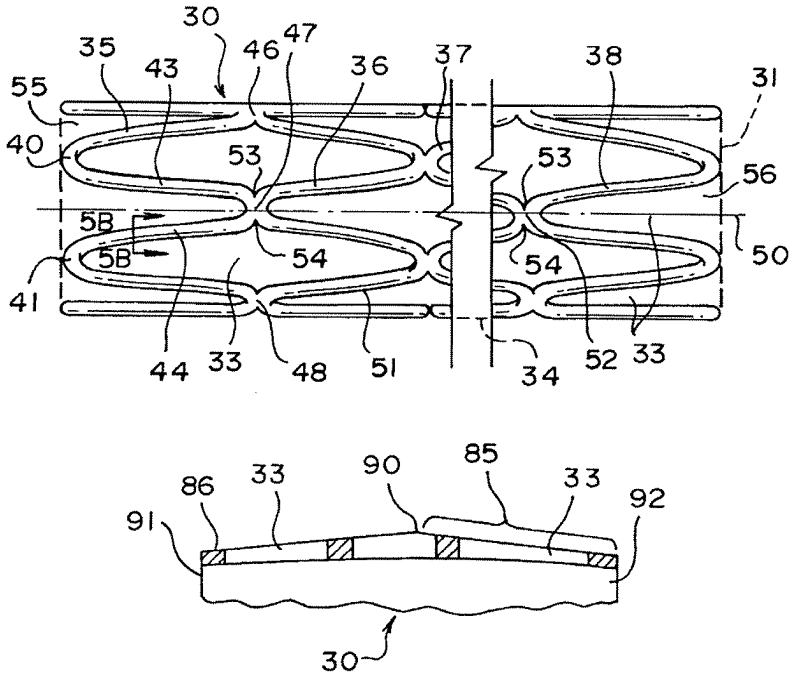
Primary Examiner—Michael H. Thaler

[57] **ABSTRACT**

A vascular or endoluminal stent adapted for deployment in a vessel or tract of a patient to maintain an open lumen therein is formed from a metal open-ended tube which is the single component of the stent. The tube has a multiplicity of holes cut by laser through its wall. The through-holes are encompassed by serpentines that constitute the wall, the serpentines extending sinusoidally each in multiple 360° wavelengths in a single turn about the axis of the tube and juxtaposed in plural substantially identical segments disposed with regularity along the axis. Each segment has a length equal to the distance between crests and troughs of the sinusoid. Adjacent serpentines are joined together at crest and trough, respectively, so that their interconnections are 180° out of phase relative to their wavelength. The serpentines and interconnections thereof are shaped throughout for optimum uniform expansion of the stent during deployment thereof, including a notch substantially symmetrically located at either side of the junction of the respective crest and trough of the interconnections between adjacent serpentines. The serpentines are substantially devoid of sharp corners and edges, except at the notches, and each serpentine has an oval cross-section. The regularity of the segments is interrupted at least once along the axis of the tube by serpentines oriented differently from the others, used to maintain the tube's length substantially invariant despite radial expansion of the stent during deployment. The serpentines are pre-stressed and annealed before deployment of the stent to ease deployment and enhance symmetrical radial expansion. The exterior surface of the tube is longitudinally tapered from its mid-point toward its ends, and substantially rounded surfaces prevail throughout the tube.

4 Claims, 3 Drawing Sheets



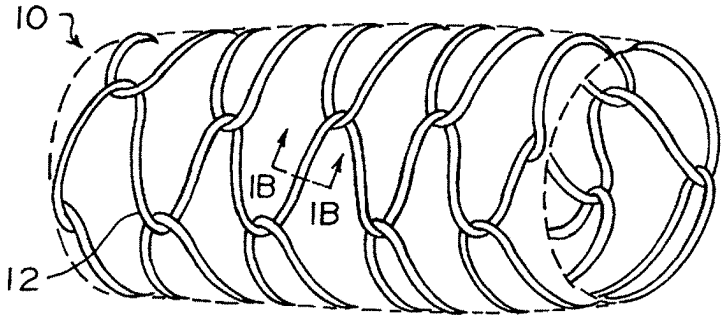


FIG. 1A
(PRIOR ART)

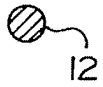


FIG. 1B
(PRIOR ART)

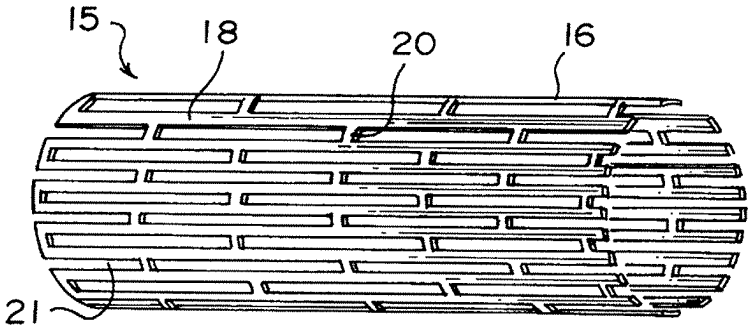


FIG. 2A
(PRIOR ART)

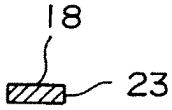


FIG. 2B
(PRIOR ART)

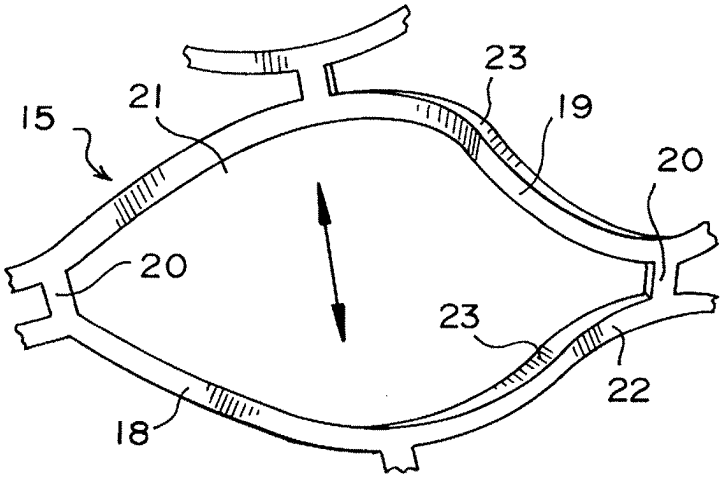


FIG. 3
(PRIOR ART)

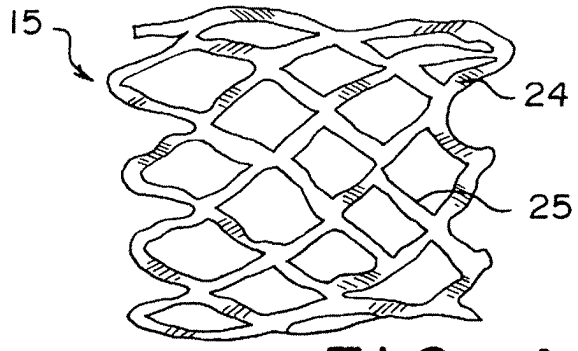


FIG. 4A
(PRIOR ART)

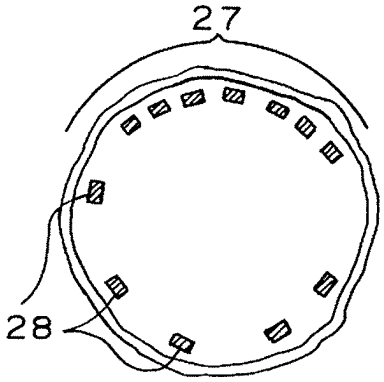


FIG. 4B
(PRIOR ART)

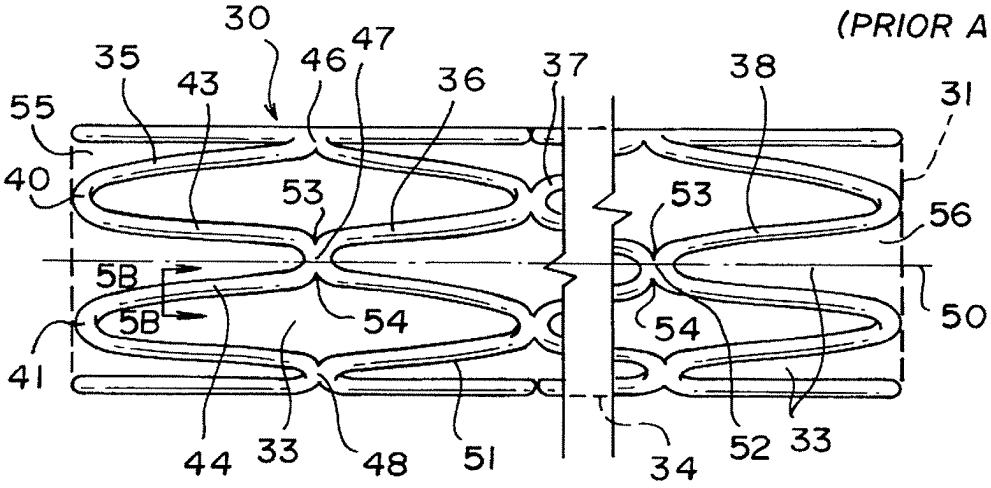


FIG. 5A

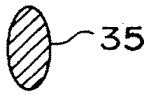


FIG. 5B

FIG. 5C

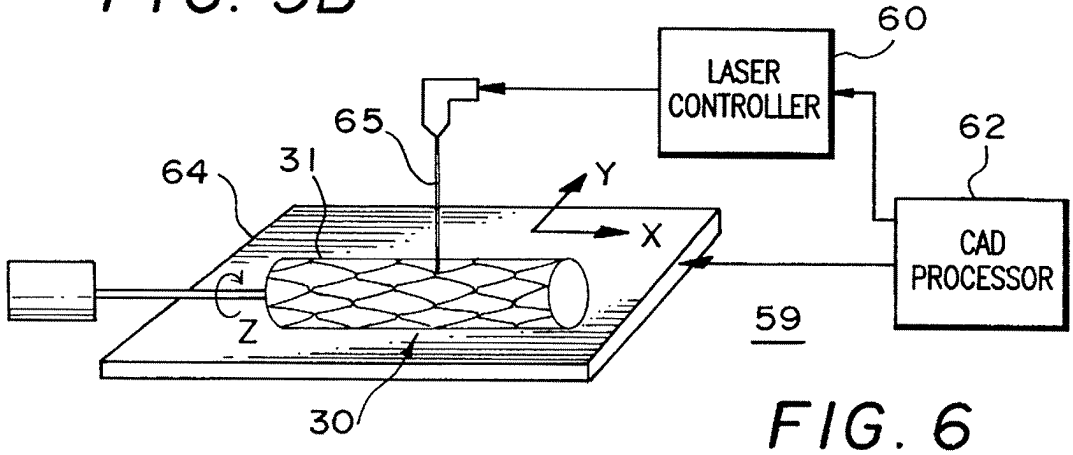


FIG. 6

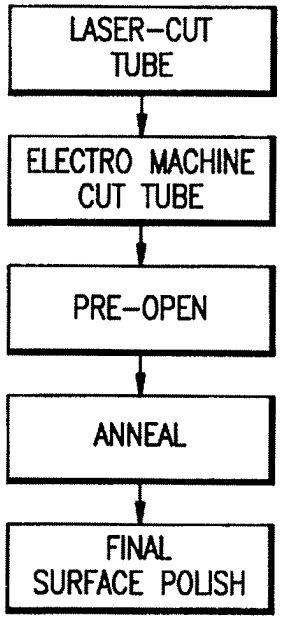


FIG. 7

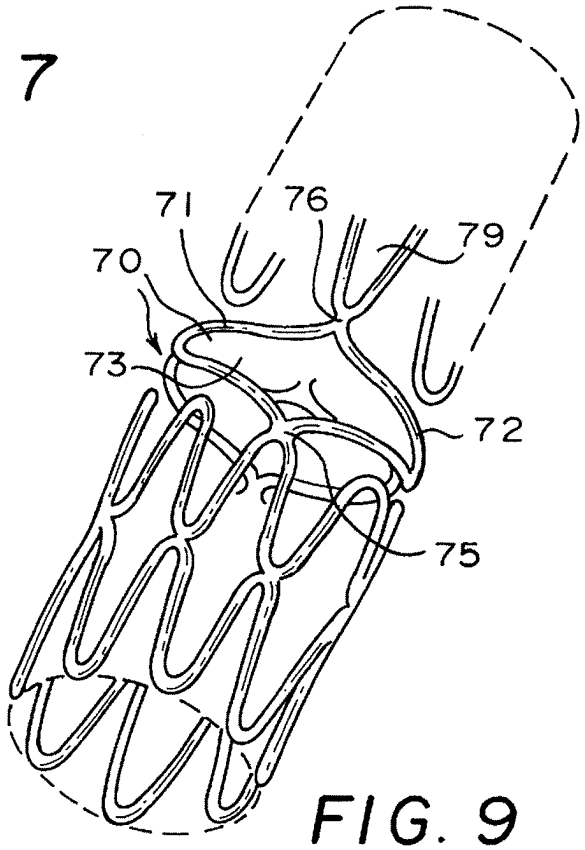


FIG. 9

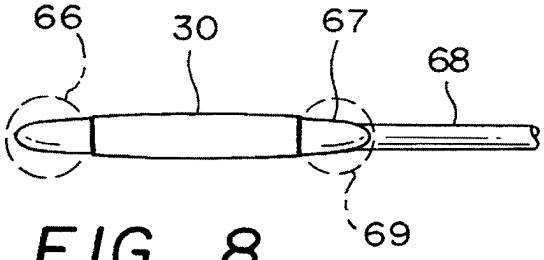


FIG. 8

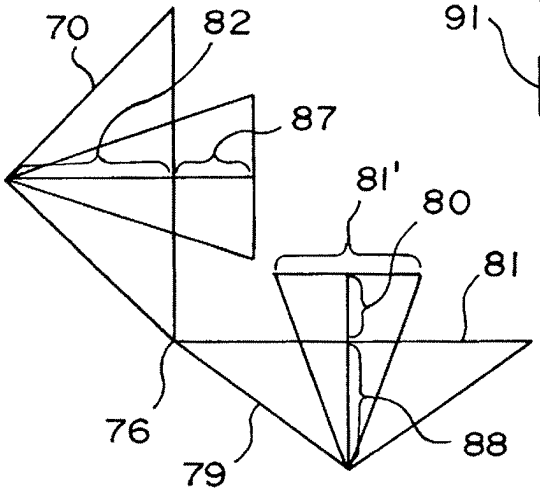


FIG. 10

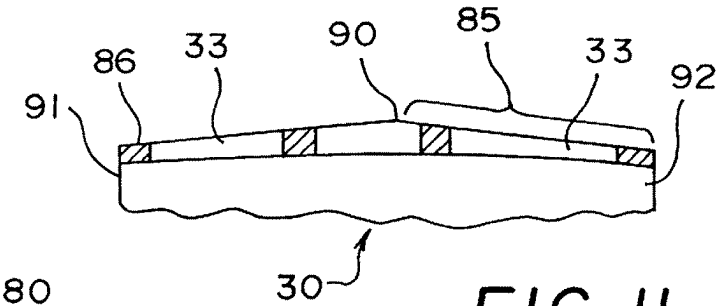


FIG. 11

IMPLANTABLE VASCULAR AND ENDOLUMINAL STENTS AND PROCESS OF FABRICATING THE SAME

BACKGROUND OF THE INVENTION

The present invention relates generally to stents which are implantable or deployable in a vessel or duct within the body of a patient to maintain the lumen of the duct or vessel open, and more particularly to improvements in stent structures, stenting procedures, and processes for making stents.

Stents are expandable vascular and endoluminal prostheses, usually employed to keep a particular site in the blood vessels open and unoccluded, especially in the coronary and femoral arteries, following treatment such as dilatation by balloon catheter angioplasty. But these devices are also quite useful in other applications as well, such as in other tracts internally of the human body where an aid is required at a target site to maintain the lumen open and unobstructed. Examples are the tracheo-bronchial system, the biliary hepatic system, the esophageal bowel system, and the urinary tract system. In general, a vascular stent in particular must be sufficiently dimensionally stable to keep the vessel and lumen open while resisting recoil of its elastic wall that naturally occurs when the site within the vessel or luminal structure has been subjected to outwardly directed forces that are necessary to expand the elastic fibers, compress fatty deposits on the wall, and/or to deploy the stent, and to prevent an acute closure following dissection of the vessel.

In practice thus far, two types of stents have predominated for clinical vascular applications. One type, exemplified by a stent available from Cordis Corporation, is fabricated from a round wire laid into a zig-zag form, described more fully in U.S. Pat. No. 4,580,568. The other type is referred to as the Palmaz-Schatz stent, manufactured from a longitudinal tubular element with a narrow central lumen, as described in European Patent EP 81-0221570. In the Palmaz-Schatz type, the longitudinal metal tubular element is open at both ends and has rectangularly shaped, longitudinally oriented openings in its wall that form a pattern of confluent intersecting struts.

These wire and tubular stents, as well as other types, are expanded to a larger diameter by application of radial forces directed outwardly from within the lumen of the stent by inflation of a precision expansion balloon of a catheter on which the stent is mounted. Typically, the balloon is coupled for inflation at the distal end of a catheter that may have several lumens, such as to permit blood perfusion, guide wire (rail) advancement, and other purposes, as well as for pressurizing (inflating) and de-pressurizing (deflating) the balloon.

In the case of a wire stent, such as that of the '568 patent, although the wire has a round cross section with relatively low risk of causing significant injury to the vessel wall, it makes only line contact with the wall at each wire segment. More importantly, this type of stent lacks the radial strength to resist forces of compression, and thus, is unable to withstand elastic recoil of the vessel wall following expansion thereof, such as after balloon angioplasty. As a result, a wire stent may suffer a loss in lumen diameter in the vessel of up to about 30%. For example, the wall of a vessel whose lumen has been expanded by balloon inflation to a diameter of 4 millimeters (mm) can undergo recoil within days to a diameter of 3 mm, despite implantation of a wire stent.

The Palmaz-Schatz stent described in the EP 81-0221570 patent has a relatively stiff structure with good resistance to compression, and therefore, the dimensional stability to resist the vessel wall's elastic recoil and maintain lumen diameter. But it has the disadvantage of presenting greater risk of injury to the vessel wall or damage to its expansion balloon because of sharp edges. Clinical practice and animal experiments have demonstrated that the sharp edges of individual struts of this type of stent can cut into the medial and intimal layers of the vessel wall. With typical stent wall thickness in the range from 65 to 100 microns, its edges are almost knife-like. A deep cut in the vessel wall from such an edge during deployment of the stent can signal disaster. Even minor scraping or other abrasion of the vessel wall from these edges or protuberances provoke the healing phenomena of smooth muscle cell hyperplasia, which leads to restenosis. Recent clinical data has shown also that the restenosis rate with this type of stent is in the range of from 25% to 35%, which lessens its advantage of rigidity against radial compression.

Also, since the stent is crimped onto an uninflated balloon of a balloon catheter for subsequent deployment, any sharp edges are prone to puncture or rupture the balloon at that time or during stent advancement through the vessel or during deployment. If the balloon cannot be inflated to the size necessary to properly deploy the stent because the membrane has ruptured or is leaking, and so leaves the stent either unopened or only partly opened, it may not be possible to retract the stent. In that case, the stent will remain in the blood vessel as an unuseful foreign body, incapable of maintaining an open lumen, and possibly to ultimately cause complete blockage of the vessel. If that were to occur in a coronary artery, it could lead to myocardial infarction, and potentially, death of the patient. In the case of loss of the stent in a femoral artery, the result could also be total obstruction and result in a significant compromise of leg blood circulation. We have observed clinical procedures where the balloon ruptured because of the stent's sharp edges when the inflation pressure exceeded three atmospheres.

Moreover, because the target site in the vessel is often deep within the vessel or body of the patient, with the necessity to advance the stent on its balloon catheter through a long, often tortuous path of normal or diseased vessel, the likelihood increases that sharp edges of the stent will cut into arterial tissue and provoke an acute closure, or compromise or prevent advancement of the stent to the target site. Here again, then, the stent must be adapted to enable it be advanced on the balloon catheter in relatively smooth, unimpeded fashion through the vessel lumen to the predetermined target site a which it is to be deployed.

It is also imperative that the stent will expand radially and reliably in a symmetric manner in response to the forces exerted on its interior surface by the inflating balloon. Several studies conducted by the applicants have shown that existing tube type stents all too often expand asymmetrically, despite application of homogeneous radial forces by the expansion balloon. We have found that a significant part of this problem is that a considerable initial force is required to induce primary bending of the struts (i.e., to overcome structural inertia), so as to displace them from initial positions primarily parallel to one another into a more net-like or rhombic position. This initial force is higher than that required for further expansion of the stent to a fully deployed position.

Typically, at least a few of the struts of the most popular existing tube type stents remain in their parallel or substantially parallel original positions during deployment of the stent, thereby forcing other struts to undergo overexpansion

with ongoing inflation of the expansion balloon, which causes asymmetric opening of the stent. The result is that some of the through holes in wall of the stent grow much larger than others, which lends them to accommodate inward protrusion of the vessel wall, impeding blood flow and causing turbulent in the region of the target or implant site. Ironically, this tends to induce restenosis which the stent was implanted to prevent.

Several clinical investigations have focused on ways to assure symmetrical radial expansion of the stent. For example, reliable symmetric opening has been sought by use of a high pressure balloons, inflatable to pressures ranging from 12 to 20 atmospheres. But this has several drawbacks, such as requiring the use of a second balloon (the high pressure balloon) at the target site, and causing additional trauma to the vessel wall which may include tearing and dissectioning that induces restenosis. A study recently completed at our clinic has shown that late lumen loss is proportionately greater when higher inflation forces are used to deploy the stent. Moreover, high pressure balloons are expensive (present-day cost ranges from about $600 to $1,000 per balloon), and like others, are not reusable.

Restenosis can originate not only at openings within the stent but at either or both of its ends where a transition exists in the lumen, from a stiff metal prosthesis to a very elastic vessel wall. At the transition region, considerable mechanical bending force is applied to the vessel wall by the presence of the stent—prompting a vascular reaction that leads to restenosis.

Although wire type stents, being more flexible, are less likely to cause this problem, they have the aforementioned inability to withstand vessel recoil. Moreover, the inadequate support of the diseased vessel wall offered by wire stents has been shown by many dissections. Wire tends to provide line support, which is inferior to the support given by the thicker, rectangular shapes typically found in the tube type stents. Wire meshes, like asymmetrically expanded tube type stents, can have very large holes that encourage inward protrusion of the vessel wall, with the same undesirable results.

All too frequently, the bending that occurs during expansion of known tube type stents causes twisting or torquing of at least some of their elongate strut members. In some instances, the twisting is attributable to weakness in the structure at locations where the struts are connected by bridges or bars of thicker or thinner cross-section, or where other regions of non-uniform thickness exist. When the struts become twisted, the vessel wall will be engaged by the stent, at least partly by the edge of the thin-walled (e.g., 65–70 microns thick) tubing, instead of the wider (e.g., 140 microns) side of the strut, with the aforementioned results of tissue or balloon membrane damage.

Also, if the physician finds it necessary to insert a balloon-mounted stent through an already-deployed stent, the order of difficulty is considerably greater where the latter has a twisted structure since it creates a region of higher friction in the lumen. This increases the possibility that the edge of the stent being deployed will become hooked distally of the existing implanted stent. The problem can occur where the site of a dissection to be stented was inadequately identified by dye, so that incomplete coverage is afforded by the stent now implanted, leaving a distally unsupported dissected region. Within a short time, typically from 5 to 15 minutes, the unstable vessel wall condition and the need to place a second stent distally of the first will become visually apparent.

It is a principal aim of the present invention to provide a stent which is less likely than those of the prior art to injure the vessel or tract wall during advancement through the lumen thereof, or to rupture the membrane of the balloon during initial mounting or subsequently while advancing or inflating the balloon for deployment, which requires less force for expansion and which expands symmetrically, and provides better protection against restenosis.

SUMMARY OF THE INVENTION

According to the invention, a vascular or endoluminal stent includes a biocompatible hollow open-ended tube as the single member from which the entire stent is fabricated, and a multiplicity of openings through the wall of the tube shaped according to a plurality of serpentine elements in the wall that run circumferentially in juxtaposed substantially sine wave-like patterns. All patterns are of uniform multiple cycles, with adjacent ones of them offset from each other by a predetermined phase difference at interconnecting points between them about the circumference of the tubular wall. The patterns are uniformly displaced longitudinally along the axis of the tube.

The phase difference at interconnecting points between adjacent longitudinally-displaced sine wave-like patterns of the serpentine elements is 180°, viewed as the offset between cyclical waves of the two, and each of the interconnecting points includes means in the form of circumferential notches between them to enhance crimping and symmetric expansion of the stent on a balloon, or means otherwise adapted to exert relatively uniform radial outwardly-directed forces from within the tube. Each of the serpentine elements has a rounded cross-section, in particular an oval cross-section. The uniform longitudinal displacement of the circumferential sine wave-like patterns is interrupted at least once along the stent's axis by transversely oriented serpentine elements that run longitudinally within the tube wall in juxtaposed at least partial sine wave-like patterns, and that serve to shape openings through the wall between them. Adjacent transverse patterns are offset from each other by a 180° cyclical phase difference at interconnecting points between them along the tube's axis. These transversely oriented serpentine elements are adapted to maintain the length of the tube substantially invariant with radial expansion of the stent.

In the stent, the phase difference at the interconnecting points between adjacent longitudinally-displaced ones of the sine wave-like patterns of the serpentine elements may alternatively be viewed as being less than 180° relative to the 360° circumference of the tube and the number of sine wave-like cycles in each of the circumferential patterns.

The tube, as structured with the serpentine elements and openings, is annealed, and has longitudinally tapered ends to more easily traverse the tortuous path typically encountered by the stent as it is advanced through the human vascular system to the target site at which the stent is to be deployed. Preferably, the wall of the tube is laser cut to cleanly form the openings and serpentine elements therein. Also, the tube is adapted for symmetric expansion of the stent by being pre-opened from its original production diameter to a second larger diameter which still falls well short of its fully deployed diameter on radial expansion.

The stent tube has substantially rounded surfaces throughout, except at the notched points, and the transverse patterns are adapted to maintain the length of the tube substantially invariant during radial expansion of the stent. An expansion balloon may be inserted into the axial lumen of the tube so that the proximal and distal ends of the balloon

extend beyond the proximal and distal ends of the stent, and the stent then affixed to the balloon by partial inflation thereof. A catheter shaft connected to the proximal end of the balloon has a lumen for inflation of the balloon, and enables advancement of the stent on the partially inflated balloon in a vessel or tract of the patient to the target site, and enables deployment of the stent by further inflation of the balloon at the site. In essence, the balloon is inflated to a pressure in the range from 0.1 to 0.5 atmospheres, to distend the balloon sufficiently at the portions of its distal and proximal ends which extend beyond the respective ends after the stent is crimped on the balloon. The crimped stent is thereby retained firmly in place on the balloon and a cushion is created for protecting the stent and preventing it from contacting tissue during advancement through the vessel or tract to the target site. The tube is mechanically biased to substantially reduce inertial forces needed to be overcome to enable substantially symmetrical expansion of the stent during its deployment.

In another respect, the stent of the invention may be viewed as a metal open-ended tube with a multiplicity of through holes in its wall encompassed by serpentines that constitute the wall, the serpentines extending sinusoidally each in multiple 360° wavelengths in a single turn about the axis of the tube and juxtaposed in plural substantially identical segments disposed with regularity along the axis. Each segment has a length equal to the distance between crests and troughs of the sinusoid, and adjacent serpentines are joined together at crest and trough, respectively, to be interconnected 180° out of phase relative to the wavelength of the immediately adjacent sinusoid. The tube is the single component of the stent, and its serpentines and interconnections are shaped throughout for optimum uniform expansion of the stent during deployment.

A process of fabricating such a stent includes cutting through a metal open-ended tube to form a multiplicity of through holes in the tube wall, encompassed by the serpentines that constitute the wall. The cutting produces serpentines that extend sinusoidally each in multiple 360° wavelengths in a single turn about the axis of the tube and juxtaposed in plural substantially identical segments disposed with regularity along the axis. Each segment is made to have a length equal to the distance between crests and troughs of the sinusoid, in which adjacent serpentines are joined together at crest and trough, respectively, which makes the serpentines are interconnected 180° out of phase relative to their wavelength.

The process further requires shaping the interconnections between adjacent serpentines which includes providing a notch substantially symmetrically located at either side of the junction of the respective crest and trough. Electro machining of the stent provides serpentines substantially devoid of sharp corners and edges, except at the notches, and gives each serpentine a substantially oval cross-section. The process also interrupts the regularity of the segments of serpentines at least once along the axis of the tube, to provide means for maintaining the length of the tube substantially invariant despite radial expansion of the stent during deployment.

A method of deploying the stent in a vessel or tract in the body according to the invention includes inflating an expansion balloon without a stent to a pressure in a range from about 0.1 to about 0.5 atmosphere to partially inflate the balloon, advancing the partially inflated balloon over a guidewire to the target site, and then retracting the balloon in an uninflated state, so as to ascertain that the passageway to the site will accommodate advancement of a stent crimped on a similar balloon inflated to substantially the same pressure. After the balloon is retracted, a stent is crimped on an expansion balloon substantially identical to the retracted balloon, the balloon is partially inflated sufficiently to distend its proximal and distal ends, as described above, without substantially expanding the stent diameter. Thereafter, the expansion balloon with the stent crimped on it is advanced to the target site, and the stent is deployed.

In a preferred method of the present invention, the openings in the wall of the biocompatible hollow metal open-ended tube are precisely cut by a laser beam, to define the desired sinusoidal pattern of the stent elements. The laser beam is preferably very narrow—about 35 microns wide or less, is extremely accurate—within tolerances of 2 to 3 microns, and is maintained motionless—except for being switched on and off as cutting is to commence and to cease. In the process, the tube is mounted as a workpiece to allow it to undergo controlled translation and rotation in three-dimensional movement produced by a known apparatus using a processor with computer-aided design (CAD) software. The programmed cuts in the wall with the laser beam not only enables precise definition of the stent pattern, but produces cuts that are virtually burr- and protuberance-free. Care must be exercised to avoid melting the material at the interior surface of the tubular wall, as well as unintended cutting of the opposite side of the tube wall, but these are not difficult safeguards with presently available laser cutting machines. This part of the process produces a relatively smooth stent structure even before special additional machining is employed.

The latter process is electro-machining that automatically concentrates a high current sufficient to attack sharp edges and corners in the tube structure for considerably greater removal of material at those points than elsewhere. This results in a desirable rounding and smoothing of all sharp corners and edges which creates a rounded, preferably oval shaped cross-section of the remaining serpentine ribs of metal that surround the openings. By eliminating sharp edges, corners, and burrs in the stent, there is considerably less likelihood of injury to the vessel wall as the stent is advanced through the vascular system to the target site where it is to be deployed, or as it is deployed, as well as avoidance of damage to and even possible rupture of the membrane of the balloon on which the stent is crimped and deployed.

In that regard, it will be understood that in practice, a guide catheter is inserted initially through the path of the vascular system to be followed by the balloon catheter-mounted stent. The path may be best described as tortuous, with curves, turns, and sharp bends likely to be encountered. Although the guide catheter is in place for most of the passageway, except into the specific designated site, such as a location in the coronary artery, any sharp edges or burrs on the stent could preclude injury-free traversal of this path, by puncturing, cutting, or tearing the guide catheter wall and then the vessel wall itself.

In the electrolytic machining process for edge- and corner-smoothing, the partially completed stent is placed in an electrolytic bath and a voltage placed across the cathode and anode of the apparatus to produce current flow of sufficiently high magnitude to achieve the desired results. Preferably, the stent itself is used as the anode. The highest current density is present at the edges and corners of the metal in the pattern defined by the openings in the tubular wall, which results in much greater removal of material in those areas than elsewhere in the structure. Up to about five times more metal can be removed at the sharp edges and

corners than at more extensive planar surfaces of the structure by appropriately selecting the time, increasingly adjusted current densities, distance between electrodes, electrode diameters, and nature (e.g., constituency) of the electrolyte, so that the edges and corners of the structure are nicely rounded.

If the laser cutting leaves some burrs on the interior surface of the tube wall which are not fully removed because of the cage effect that inhibits electrolytic machining on the inside surface of the tube when electrodes are external to the tube, or if additional rounding of edges at the inside surface is desired, further electro-machining may be performed in which the cathode is a pin that protrudes inside the tube. Periodically, alkaline deposits in the bath arising from the process can be removed by adding acid to enhance the electrolyte, and then conducting further electro machining to produce a shiny, smooth surface throughout the stent.

Animal studies conducted by the applicants herein have clearly demonstrated the importance of rounded elements in the stent, especially the ends and exterior wall surface, to enable easier advancement of the stent through the vessel's tortuous passageway. The arteries are elastic structures that undergo constant contractions and movement, which makes the rounding of even greater importance to avoid injury to this undulating vascular structure.

The basic sinusoidal, sine wave, or sine wave-like pattern of the serpentine elements of the stent are created by the programmed laser cutting of the tube wall. In the preferred embodiment, openings are predetermined to form continuous serpentine ribs lying longitudinally or transversely in the tubular wall. The preferred configuration is one of generally circumferentially oriented serpentines or serpentine elements extending sinusoidally about the axis of the tube in repeating, longitudinally displaced segments along the axis, encompassing the multiplicity of through holes in the wall, and thereby constituting the wall itself. The sinusoidal or sine wave-like pattern of each segment or row of serpentines along the stent axis is composed of multiple 360° wavelengths or cycles of the metallic element in a single turn about the axis, preferably of uniform wavelength. Accordingly, the sinusoidal circumferential patterns are juxtaposed in plural, substantially identical segments disposed with regularity along the axis. Each segment has a length equal to the distance between crests and troughs of the sinusoid, and adjacent serpentines (i.e., adjacent rows of the patterns) are joined together at crest and trough, respectively. Thus, adjacent serpentines are interconnected—periodically joined—at points 180° out of phase relative to their wavelength.

An alternative way of viewing this structure is that if, say, twelve cycles of the sinusoid lie in each segment, the adjacent serpentines are interconnected every 30 degrees (i.e., twelve times) in the full 360° circumference of the tube. The tube is the sole component of the stent, which makes its structure of critical importance to achieving the characteristics of ease of substantially uniform crimping onto a balloon, relatively low force radial expansion, and substantially symmetric opening upon deployment at a preselected site. The serpentines and their interconnections are shaped throughout the length and circumference of the tube wall for optimum achievement of these characteristics, which represent a considerable advance over the prior art. Undesirable events all too often encountered in heretofore available stents, such as twisting of struts that can result in abrasion or cutting of the wall of the blood vessel (or other tract or duct in which the stent is to be deployed) or of the membrane of the expansion balloon, or asymmetric opening of the stent to offer inadequate support of the vessel wall and increased risk of thrombosis, are considerably less likely to occur during deployment of stents of the present invention.

No welds or other special fasteners or questionable joints are present in this stent to interrupt its smooth, continuous structural pattern, which provides the strength and rigidity of tubular construction for desirable full support of the wall of the vessel or tract in which it is deployed, while offering reasonable yieldability for smooth crimping and expansion and flexibility for placement. In the latter respects, the interconnections of adjoining serpentines are preferably characterized by provision of circumferential notches at either side of the junctions between confronting crests and troughs about the juxtaposed segments, and the exterior surface of the wall of the tube is preferably tapered toward its open ends.

The enablement of low force radial expansion of the stent when it is to be deployed is further assisted by subjecting the stent to pre-opening, which pre-stresses or mechanically biases it to eliminate a subsequent need to overcome the inertia of first time expansion during deployment. In this respect, the stent has a first production diameter (i.e., existing at the outcome of the basic manufacturing process), and a second fully deployed diameter (i.e., to which it is radially expanded in the vessel at the target site). The pre-opening of the stent is performed after the basic manufacturing process has been completed, so that the stent as delivered for use has a third diameter intermediate the first and second but still considerably smaller than the second, which enables both ease of crimping and ease of radial expansion.

For example, the initial diameter of the stent lumen may be 1.6 millimeters (mm). Pre-opening of the stent is performed by placing it over a rotating needle so as to increase the lumen diameter to a dimension preferably in the range of from 2.0 to 2.3 mm for vascular uses. A larger pre-opened diameter may be desirable for stent usage in other tracts. This extends the serpentines circumferentially in a uniform manner, causing them to flatten slightly and simultaneously expanding the openings through the wall into a slightly rhombic shape. The pre-opening process thus provides a useful test of the adequacy of likely performance of the device during deployment. If a stent fails to undergo symmetric opening in this partial expansion, it will be deemed unworthy as a production device suitable for implantation, and hence, rejected.

As one of the final steps in the fabrication process, the metal stent is annealed to provide it with additional radial strength without adversely affecting the longitudinal flexibility of the structure. The annealing step is preferably conducted after the pre-opening of the stent but may alternatively be performed beforehand.

The stent characteristics of ease of full and symmetric expansion remain despite an initial crimping of the stent onto the expansion balloon, either by the physician at the time the stent is being implanted, or by the manufacturer if a pre-assembly of the stent on the balloon is to be supplied for use. This highlights a further advantage of pre-opening the stent—namely, that the balloon is more easily inserted into the stent than would have been the case had the stent been left with its original diameter (basically, that of the starting tube). Also, if the serpentine structure is annealed in the pre-opened condition, the metal tends to be relaxed in that state. Before the crimping, the balloon is put under vacuum to assure a more complete securing of the stent on the balloon. Afterward, the balloon is partly inflated to stabilize the location of the stent intermediate the ends thereof as mounted on the balloon.

The importance of a symmetric opening of the stent as it is being deployed at the target site cannot be overemphasized. With a stent according to the present invention, symmetric expansion is achieved with even low pressure balloons, at pressures in the range of from 6 to 8 atmospheres. A single balloon can therefore suffice for mounting of the stent, advancing it to the target site, and deploying it. The primarily longitudinal, flattened oval-like openings defined by the circumferential serpentine elements of the stent are readily shifted during deployment to a rhombic or net-like shape. Symmetric opening gives much greater likelihood of a successful vascular stent deployment without injury to the vessel, with stabilization of the vessel wall, and with greater probability of avoiding restenosis. Results of corresponding importance are achieved with endoluminal stents for use in other tracts of the body.

To provide the tapering of the outer diameter of the tube toward its open ends, the tube is polished in a smooth progression from its mid-section. This gives it improved flexibility at the ends and greater compliance with the wall of the vessel at the implant site. The uniform diameter of the tube's axial lumen is substantially unchanged throughout its length by this process, so as to avoid impeding or creating turbulence in the blood flow that might otherwise cause thrombus formations.

The stent of the present invention is adapted to automatically compensate for a reduction in its length otherwise occasioned during deployment by radial expansion. In essence, the stent is provided with means for maintaining its length invariant despite the opening of its diameter. The preferred means for performing this function comprises serpentine elements structured to undergo a change in length in a direction opposite that caused by the partial flattening of the circumferential serpentines with the increased diameter of the stent. Alternative means could include, for example, the use of selected thinner-walled regions to facilitate unequal movement of members for length compensation purposes. While no particular difficulty is encountered to fashion elements of different thicknesses a the same time that other features of the stent design are constructed, by use of a 3-D workpiece and CAD-2 controlled laser system, in the preferred embodiment serpentine elements are provided in the tubular wall in transverse orientation relative to that of, and in at least one location intermediate, the circumferentially running serpentines, as the compensating means. The transverse serpentines are connected to selected points of the most closely adjacent circumferential serpentines and are also of sinusoidal pattern, but run longitudinally and are separated from one another at predetermined points about the circumference of the tube. The selected separations avoid imposing constraints on the diameter of the stent at the location of the transverse elements during expansion of the stent, but do not substantially affect the rigidity of the stent. During crimping of a stent with such length-compensating means onto a balloon, additional care is required for uniform crimping of unconnected portions of the compensating sections.

The stent's automatic maintenance of substantially its original length during deployment makes it unnecessary for the physician to pre-calculate or otherwise determine changes in length of the stent to assess adequacy of coverage of the affected tissue at the target site in the vessel. Additionally, the length-compensation feature lessens the likelihood that two stents must be implanted end-to-end where, but for a change in length, a single stent of standard length would suffice.

Further distinctions of the present stent from prior art stents include the following. Comparing the preferred embodiment with wire stents, the width of the support structure elements—here, the serpentines—is about 140 microns, with twelve full wavelengths or cycles in each row about the circumference of the tube. Hence, the total area of support afforded by the present stent is much greater than that provided by a wire stent with its typical four or five wire segments about the periphery. Further, the support offered involves more than simply the width of the wall elements. For example, if each serpentine has a width of 140 microns and a thickness of 70 microns, the width to thickness ratio is a factor of 2:1, with achievement of full mechanical strength. The diameter of the wire in a typical wire stent of the type referred to above is in a range from about 150 to 180 microns. The coronary arteries have diameters as small as 2.0, 2.5, or 3 mm. The tubular wall thickness (and therefore, the individual element thickness) of the present stent can be significantly increased without loss of its lumen size advantage over the wire stent. For example, the difference between the wire diameter (doubled, as the thickness occupies "both sides"—actually the entire surface of the vessel wall, when viewed in a cross-section through the vessel's lumen) and the serpentine's thickness (also doubled) is about 200 microns (or 0.2 mm), which may range from about 6% to about 10% of the total diameter of the vessel. The stent of the present invention thus offer a substantial advantage in size of passageway for blood flow over that available with the typical wire stent, and would continue to do so with increase in wall thickness of up to 100 microns.

Compared to tube-type stents currently in common use, the present stent does not use a system of parallel longitudinal struts and connecting bridges—instead, using serpentines of sinusoidal pattern running circumferentially—nor have rectangular openings in the tube wall as with the prior stents, instead producing a rhombic, net-like structure. Rather than having elongate members joined by distinct bars or bridges, the present stent's serpentines enjoy periodic smooth interconnection in an integrated structure, with circumferential notches to facilitate both crimping and radial expansion. Cross-sections are rounded, preferably oval-shaped, rather than sharp. Additionally, because the present stent is provided for use in a pre-opened condition or state, and no intersecting elongate members as such are present, a slightly spring-like reaction occurs when the stent is crimped, but the stent undergoes smooth and symmetric expansion with no undesirable elastic recovery during deployment. At points of interconnection between adjacent serpentines, considerable pressure may be exerted to firmly crimp the stent on the balloon without concern for the sharp edges often found in prior art stents that might cut into the balloon's membrane.

In preparation for implantation, the stent is crimped on and intermediate the ends of a deflated expansion balloon, and the balloon is then inflated to a pressure of from about 0.2 to about 0.4 atmospheres, sufficient to distend its end portions that extend beyond the respective ends of the stent without substantially expanding the crimped stent thereon. This technique of firmly attaching the stent on the balloon serves several purposes. First, any slipping or dislocation of the stent relative to its initial crimping site is avoided both before and during advancement to the target site in the vessel or tract. Firm retention is important here because the stent is not very visible during the procedure, reliance being placed instead on the position of a radiopaque marker dot on the balloon which is visible by X-ray and identifies the original relative location of the stent. Inaccurate placement of the stent for deployment will occur, however, if the stent slipped along the balloon during the journey to the target site, with

resultant failure to cover the full site of the injured tissue, leading to a need to implant a second stent or leaving a prime site for restenosis.

Second, the slightly inflated end portion of the balloon ahead of the crimped stent prevents the stent from cutting into arteriosclerotic vessel portions as the stent is advanced to its target site. Third, if an inability to advance the stent to its final destination is encountered, such as because of very sharp bending of the arteries, the stent can be retracted into the guiding catheter, protected by the other slightly inflated end portion of the balloon, without substantial risk that the stent will be stripped from the balloon and left in the vascular system, possibly leading to infarction.

In a preferred test run, an expansion balloon without stent is partially inflated to a predetermined pressure such as the 0.2 to 0.4 atmosphere range, is then advanced over a guidewire to the target site, and then depressurized and withdrawn in the uninflated state from the site and from the vascular system. If the path is found by this method to be open and unimpeded, the procedure may be repeated with a stent on a substantially identical balloon inflated to a substantially identical pressure with greater assurance of its success.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and still further aims, objects, features, aspects and attendant advantages of the present invention will become apparent from the following detailed description of a preferred embodiment and process of manufacture thereof constituting the best mode presently contemplated of practicing the invention, when taken in conjunction with the accompanying drawings, in which:

FIG. **1A** is a perspective view primarily from the side, and FIG. **1B** is a cross-section of an individual wire, of a wire-type stent of the prior art;

FIG. **2A** is a partial perspective view, primarily from the side, of a prior art tube-type stent, and FIG. **2B** is a cross-section of an individual strut thereof;

FIG. **3** is a fragmentary perspective view of a portion of the prior art tube-type stent of FIG. **2A**, during expansion for deployment in a vessel;

FIG. **4A** is a perspective view of the prior art tube-type stent of FIG. **2A** in its expanded state, and FIG. **4B** is a cross-section view through a vessel with that opened stent;

FIG. **5A** is a side view of a vascular or endoluminal stent according to the present invention, in a pre-opened state for use; and FIGS. **5B** and **5C** are cross-sections through a serpentine illustrating preferred and alternative shapes;

FIG. **6** is a diagram partly in block form and partly in schematic representation form, of apparatus for performing the laser cutting portion of the stent fabrication process of the invention;

FIG. **7** is a flow chart of the basic stent fabrication process of the invention, exclusive of the pre-opening of the stent;

FIG. **8** is a side view of a stent mounted on a balloon, with an exaggerated phantom portion illustrating the technique of the invention of partial inflation of the balloon to expand its ends for retention and delivery of the stent for deployment;

FIG. **9** is a perspective view of a stent illustrating incorporation of length compensating means into the stent structure;

FIG. **10** is a diagrammatic representation of length extension versus length contraction in the structure, to illustrate compensation performed by the structure of FIG. **9**;

FIG. **11** is a fragmentary side view of the stent of FIG. **5**, illustrating the taper in the outer diameter of the stent from the mid-section thereof toward either end.

DETAILED DESCRIPTION OF THE PRESENTLY-PREFERRED EMBODIMENT AND METHOD

Before commencing the detailed description, several comments should be made regarding the Figures of drawing. The drawings are not intended to be to scale. Where appropriate, the representations are simplified, such as in FIG. **1A**, the omission of the other side of the stent which could obviously be seen in this view but would unnecessarily clutter and obscure the portion of interest, and in FIG. **2A**, the detail supplied in only a part of the stent although it will be understood that the same pattern would be present throughout. In some instances, the Figure or a portion thereof is exaggerated for emphasis.

Referring to FIG. **1**, a prior art wire stent **10** is illustrated in side view in part A of the Figure, and the round cross-section through an individual wire **12** of the stent is shown in part B. The wires **12** are interconnected in a zig-zag pattern similar to that of a chain-link mesh used for fences. The wire diameter is large but despite this, there is only what amounts to line contact between the individual wires and the tissue of the vessel wall when the stent is fully deployed. Some of the disadvantages of wire-type stents have been described above.

In FIG. **2**, part A, a tube-type stent **15** is fabricated from tubing **16**. A plurality of parallel, longitudinally oriented struts **18** (in the unopened state) interconnected by bars or bridges **20** at intersections of the struts define a multiplicity of through-holes **21** in the wall of the tube. Greater detail may be seen in the fragmentary portion of FIG. **3**, although there the part is in the opened state. Part B of FIG. **2** illustrates the rectangular cross-section through a strut **18**. Here, also, the drawbacks of this currently highly popular type of stent have been discussed above.

However, one of the more critical aspects of the stent of FIG. **2**, namely, its ability or inability to open symmetrically during deployment, is graphically illustrated in the fragmentary diagram of FIG. **3**. Common elements in these and others of the Figures are represented by common reference numbers. As shown in FIG. **3**, stent **15** is in process of being deployed. As a consequence of structural deficiencies of the stent of this example, upon expansion of the diameter of the stent under pressure exerted on its interior surface by inflation of an expansion balloon (not shown) on which the stent is mounted, at least the initial parts of two of the struts **18**, namely **19** and **22** in this example, have undergone twisting or torquing. This deformation has exposed virtually the entire length of the thin edge **23** of each of struts **19** and **22** so as to actually or potentially contact either the interior surface of the wall of the vessel in which the stent is being deployed or the external surface of the membrane of the expansion balloon. This twisting occurs at initial expansion of the stent at pressures between 2 and 4 atmospheres.

If a few of the struts, such as only two to four of the struts undergo twisting, the remaining struts will stay in a primarily parallel configuration. That is, some of the struts are extended from their initial positions, while others have yet to open. The struts that have yielded will tend to continue to do so, which in turn tends to keep the others unopened. Further increase in balloon size and pressure will open the already deformed and twisted segments even more, resulting in a considerable and dramatic unequal and non-uniform opening of the individual stent struts, graphically illustrated in FIGS. **4A** and **4B**. The stent **15** (FIG. **4A**) is misshapen as some of the struts such as **24** have undergone little movement or extension, while others such as **25** have therefore

been caused to overextend and twist in the manner shown in FIG. 3. In FIG. 4B, the cross-section through the wall of the vessel in which the stent is deployed or being deployed reveals that a cluster **27** of the struts remain substantially unopened, while the other struts **28** are primarily overextended. The holes **21** in the stent will therefore also have assumed various non-uniform shapes and sizes as a result of the asymmetric expansion. While it is certainly possible that this stent as deployed may not cut or abrade tissue or puncture the expansion balloon, it appears to be destined to produce deformation of the vessel wall, and to create turbulence in the blood flow through its region of the vessel which can produce thrombus formation.

Referring now to FIG. **5A**, a stent **30** designed and fabricated according to the present invention, is shown in a pre-opened state as it would be supplied in volume to hospitals, medical centers, clinics, and other appropriate facilities for implantations by physicians. Stent **30** is constructed from a hollow biocompatible metallic tubular structure or member **31** (shown in phantom). The tubular member is provided with a multiplicity of openings **33** through its wall **34** which define the stent configuration. The openings **33** are precisely cut, for example, within a tolerance of 2 to 3 microns, by a narrow laser beam, on the order of 35 microns or less.

According to the invention, the biocompatible hollow open-ended tube **31** is the sole member from which the entire stent is fabricated, and the configuration defined by the multiplicity of openings **33** through the wall comprises a plurality of serpentine elements **35**, **36**, **37**, **38**, and so forth, in the wall that run circumferentially in juxtaposed substantially sine wave-like or sinusoidal patterns. All patterns are of a uniform number of multiple cycles—six in this exemplary embodiment (i.e., one cycle constitutes a full wavelength or 360° of the sinusoid—for example, from the crest **40** to the adjacent crest **41** in serpentine **35**, but there are effectively two portions, e.g., **43** and **44** in each wavelength). A 360° wavelength of the sine wave is not to be confused with the 360° circumference of the stent tube. Adjacent ones of the serpentines, such as **35** and **36**, are offset from one another by a predetermined phase difference at periodic interconnecting points such as **46**, **47**, and **48** between them about the circumference of the tubular wall **34**. The patterns are uniformly displaced in juxtaposed segments or rows longitudinally along the axis **50** of the tube, and these segments may be viewed as occupying a length of the tube substantially equal to the distance between the crest and the trough of the respective serpentine, such as from **40** to **47** in the case of serpentine **35**.

The phase difference at interconnecting points such as **48** between adjacent longitudinally-displaced sine wave-like patterns of the serpentine elements, such as **35** and **36**, is 180°, viewed as the offset between cyclical waves of the two. This phase difference may alternatively be viewed as being less than 180° relative to the 360° circumference of the tube and the number of sine wave-like cycles in each of the circumferential patterns, such as 30° for the number of cycles of the sinusoidal pattern in the exemplary embodiment of FIG. **5A**.

Each of the interconnecting points, such as **52** between serpentines **37** and **38**, includes means in the form of circumferential notches such as **53** and **54** at either side of the respective interconnection to enhance crimping and symmetric expansion of the stent on a balloon, or means otherwise adapted to exert relatively uniform radial outwardly-directed forces from within the tube. Each of the serpentine elements has a rounded cross-section, preferably an oval cross-section as shown in FIG. **5B** for serpentine **35**.

Preferably, the flattened, closed, substantially oval-shaped openings **33** are sized in a range of ratios of length to width of from 4:1 to 10:1. The length of each opening **33** is typically in a range from about 2.0 to about 4.0 mm, and the width in a range from about 200 to about 300 microns. The width of each serpentine rib **38** is preferably from about 120 to about 240 microns, and the thickness in a range from about 65 to about 100 microns depending on the specific point of along the length of the stent at which the measurement is taken, if the thickness of the tube wall is varied from middle to each end to taper the outer diameter of the stent toward the ends.

Each end **55**, **56** of the tube **31** is a series of undulations in the sine wave-like pattern of the serpentine occupying that respective segment in the basic stent structure of the invention.

Although an oval cross-section of the serpentines (shown in FIG. **5B**) is preferred, produced in part as a result of electro machining to be described below, the serpentines may have a different rounded cross-section if desired. For example, they may be shaped by the laser cutting and subsequent electro machining to be similar to an erythrocyte or a bone, rounded but with narrower mid-section and thicker ends, as shown at **57** in FIG. **5C**. Laser machining processes can also be used not only to cut out the shapes of the openings but also to narrow the mid-portion of the width of each rib in that manner. Such shapes enhance the flexibility and thereby ease of advancement and extension of the stent within the vessel, without adversely affecting the dimensional stability of the stent that assures its ability to withstand compression in response to recoil of the vessel wall.

As shown in FIG. **6**, the apparatus **59** for producing the openings **33** and the serpentines such as **35** associated with them in stent **30** includes a laser **60** controlled by a CAD processor **62**, and a worktable **64** adapted to produce 3-dimensional movement of a workpiece along or about at least three distinct axes, X, Y, and Z. In particular, the laser is oriented to direct a laser beam **65** upon a workpiece for program-controlled cutting and machining thereof. Here, the workpiece is moved along or about the axes, and the laser beam is held fixed on the space occupied by the workpiece—except for being switched on and off as cutting is to commence and to cease.

In this process, the tube **31** which is the starting material for stent **30** is mounted as the workpiece in apparatus **59** to allow it to undergo controlled translation and rotation in three-dimensional movement. The movements of tube **31** are controlled by a program developed to achieve the serpentine patterns of the stent **30**, while the laser beam **65** is switched on and off as necessary to produce the programmed precision cuts in the wall **34** of the tube. All cuts are made within time intervals and tolerances necessary to complete the cutting of the openings **33**, including the partial openings at both ends **55**, **56** of the tube, and thereby the cutting of the serpentine patterns, substantially free of burrs and protuberances. The resulting partially completed stent **30** is a relatively smooth structure as a result of its process of fabrication, but according to the invention, further machining is performed to eliminate all sharp edges and corners of the structure.

To that end, the partially completed stent is subjected to electro machining by an electrolytic process, such as that available through AVT Corporation of Germany. Alternatively, similar results may be possible with electrical discharge machining. In the electrolytic process, the par-

tially completed stent is immersed in an electrolyte bath as the anode, and a voltage is applied across the stent and the cathode to produce a high current density—up to several hundred amps at a mean rate of 15 seconds for the internal and external surfaces of the tube—through the electrolyte. The heaviest concentration of current density is at the discontinuities of the stent structure, i.e., sharp edges, sharp corners, burrs, projections, and the like, which removes metal at those points and regions at about five times the removal rate for large planar regions.

Both internal and external surfaces of the tube wall are subjected to the high current, the latter by inserting the cathode into the axial lumen of the tube as the anode. The electrolyte is of known type that will not boil while supporting current densities necessary to produce uniform rounding of the stent structure. As a consequence of this action, the stent structure is rounded and smoothed at all of its corners and edges. Further, by replenishing acid in the electrolyte depleted by the processing, followed by additional electro machining, a shiny, smooth surface is provided over the entire stent structure.

At this point in the processing, the stent **30** is composed of a plurality of continuous serpentines juxtaposed along the tube in circumferentially extending sinusoidal patterns that surrounding respective groups of the openings **33** in a completely smooth, rounded metal structure, essentially as shown in FIG. **5**A. However, FIG. **5**A is also intended to illustrate the pre-opened characteristic which is an important part of the stent fabrication process. The circumferential notches **53**, **54** at confronting midpoints of the interconnections such as **52** (FIG. **5**A) of respective crests and troughs of the adjacent serpentines are of special importance for an equal and symmetric opening of the stent and also to allow a firm crimping of the stent onto the uninflated balloon. To that end, the notches my be protected from subjection to the electro machining process to prevent them from being overly smoothed, or may be recut after that portion of the process.

On completion of the electro machining portion of the stent fabrication process, the stent is opened to a limited extent to eliminate the inertia that prevails with a first-time expansion of the stent. This partial expansion, termed the "pre-opening" of the stent herein, is effective to relieve stresses or to pre-stress the overall structure. In effect, the tube is mechanically biased to substantially reduce the forces needed to overcome inertia and to enable substantially symmetrical expansion of the stent during its deployment. If the initial outer diameter of the lumen of the stent is 1.6 mm, which in any event should correspond to the outer diameter of the starting tubular material, the pre-opening expansion process may consist substantially of positioning the stent on a rotating needle (not shown) which operates to increase the lumen diameter so that the outer diameter of the pre-opened stent may be at any of a continuum of predetermined dimensions up to that corresponding to the largest diameter available using the rotating needle. Preferably, for a starting diameter of 1.6 mm, the pre-opened diameter is at the lower end of the range from 2.0 to 2.3 mm. In any event, the pre-opening should result in an inner diameter of the stent which allows the stent to slide comfortably over the uninflated balloon, and then to crimp the stent onto the balloon.

The annealing of the stent at this point in the overall stent fabrication process is performed by heating the serpentine structure to a temperature that depends on the material from which the original tube was produced, for a predetermined interval of time. Suitable materials include medical grade stainless steel, such as 316L stainless steel, tantalum, titanium, platinum, and iridium. Even a suitable polymer of appropriate physical, mechanical and X-ray characteristics may be used, subject to the availability of a substitute process analogous to electro machining—which would not work for a non-metal—to round the corners and sharp edges of the partially processed stent. The pre-opened stent is depicted in the structure of FIG. **5**, and this form as annealed is the preferred form of device delivered for implantation by the physician, except for the inclusion of length compensating means to be described presently.

The fabrication process employed to produce the basic stent as described thus far, is illustrated in the flow chart of FIG. **7**, which requires no further explanation.

Alternatively, the completed stent **30** may be pre-mounted on a balloon **67** of a catheter body **68**, as shown in FIG. **8**, and delivered in a sterile package as a complete assembly ready for use by the physician. The principal advantage of such an assembly is that it eliminates the need for skill in crimping the stent onto the balloon, which requires sufficient experience to avoid damage to the balloon by an overly tight crimp, or the possible separation of the stent or injury to the vessel wall by an overly loose stent. The pre-mounted device need simply be unpackaged and used to implant the stent. However, each patient differs from the next insofar as vessel diameter and condition are concerned, which may necessitate the use of different balloons despite the possibility that the same type of stent could be employed in each case. Indeed, twenty different types of balloons, for example, might be usable with a single type of stent. The availability of an expansion balloon of particular dimensions and characteristics with a stent also of particular dimensions and characteristics each time a procedure is to be performed could require a considerable inventory of different pre-mounted stent/balloon assemblies.

Moreover, it may happen that the same type of balloon—of medium compliance—can be accommodated by a vessel of 2.5 mm or one of 3.2 mm, simply by inflating to higher pressure. Also, some balloons are more amenable to advancement or retraction through sharp bends in the vessel lumen but do not tolerate high pressures, while other balloons have greater stiffness and ability to withstand higher pressures. Therefore, to customize the therapeutic decision on an individual basis, it is preferable for the physician to have available stents which can be selected individually and mounted on a desired type of balloon, also selected individually, based on the physician's familiarity with each and desire to provide the optimum results for a particular patient and vascular structure and condition. Consideration of balloon characteristics including size, construction, membrane material and other properties, and other specific patient factors including implant target site, vessel sizes, length of the tissue region to be treated, and so forth, will be part of the selection process.

Whether supplied unmounted, or pre-mounted on a balloon, the stent after crimping onto the selected balloon should have an outer diameter ranging from about 0.9 to about 1.2 mm. When fully deployed in the vessel at the target site by inflation of the expansion balloon, its outer diameter will typically lie in a range from about 2.5 to about 5.0 mm, with a maximum of about 6.0 mm. Final deployed diameter, of course, must be adequate to assure retention of the stent in the vessel in firm contact with the vessel wall (and, if desired, even partly imbedded in the vessel wall to present a relatively smooth continuous lumen to lessen the possibility of blood flow turbulence).

The dimensions of the serpentines and of the openings between them in the tubular wall of the stent, as well as the

characteristics of the balloon, will ultimately determine the minimum diameter to which the stent may be crimped on the balloon—typically, 1.0 mm—and the maximum diameter to which the stent may be dilated by the balloon during deployment—typically, 6.0 mm (inner diameter).

The stent may be produced in lengths ranging from about 5.0 to about 25.0 mm. But stents of the various prior art types are typically supplied in two standard lengths, one of which is toward the lower end of the range (e.g., a length of about 8.0 to about 9.5 mm) and the other in the mid to higher end (e.g., a length of about 15.0 mm), because the expansion balloons for deploying the stents are customarily available in a length of either about 10 mm or about 20 mm. Other stent lengths are available on a custom basis, but occasionally it is necessary to implant two stents actually or virtually abutting each other when the length of the injured tissue at the target site is greater than accommodated by a single available length, or because the stent length is limited by a need for sufficient flexibility to be advanced through the vascular system to the target site.

Referring again to FIG. **8**, for purposes of implanting the stent according to the invention, the stent **30** is crimped on expansion balloon **67** with the balloon under vacuum, and then the balloon is initially inflated to a pressure of from about 0.1 to about 0.5—nominally, 0.2—atmospheres. The specific pressure selected should be sufficient to partially inflate and distend the balloon at its distal and proximal ends which extend beyond the respective ends of the stent (by proper selection of stent and the balloon lengths as illustrated by exaggerated bulbous or distended ends **66** and **69** of the balloon shown in phantom), but insufficient to expand the diameter of the stent as crimped on the balloon. With this slight inflation at its ends, the balloon provides a desirable cushion to protect the stent, to prevent it from being dislodged, and to keep it from scraping the vessel wall during advancement to the target site, by retaining it firmly centered along the balloon's length, as well as for other purposes mentioned earlier herein.

In practice, a slightly inflated balloon (to about 0.2 atmospheres pressure)—without stent—is advanced over the guidewire to the target site in the vessel where the stent is to be deployed. This "dummy" balloon is then depressurized and retracted from the vascular system and from the guide catheter. The purpose of this exercise is to ascertain that the target site is accessible through this path with a partially inflated balloon. If the access is achieved, the physician knows that a stent crimped on the balloon, which is then partially inflated as described above, can also be advanced to the target site. In part, this is assured because, given the same inflation pressure, a balloon without stent has a larger diameter than when it carries a crimped stent.

The proper inflation pressure for the balloon for this purpose depends to a great extent on the composition and characteristics of the balloon membrane—for example, whether it is polyurethane, polyimide, or some other material, whether it is highly flexible or somewhat stiff, and its length. Also, the physician should visually inspect the assembly of the stent crimped on the balloon before it is inserted and advanced in the vessel, to determine how it behaves with the lowest pressure deemed suitable for stent retention. If the pressure gauge is inaccurate at the low pressures of from 0.1 to 0.5 atmosphere, the physician must determine the "right" pressure empirically, by look and feel, which requires some experience in using and implanting stents.

Another advantage of partial inflation of the balloon for delivery of the stent is that the mounted stent is readily withdrawn if problems—such as sharp bends in the vascular path—are encountered during attempted advancement. In contrast, if the stent is being retracted while crimped on an uninflated balloon, extreme care is required to assure that the stent will not be dislodged while moving through the coronary artery are any other curved portion of the path through the vascular system, or when retracting the balloon and the stent into the guiding catheter. The edge of the stent may, for example, hook into the opening at the distal end of the guiding catheter. But if the stent is retained at approximately the middle of the partially inflated balloon, it is more easily withdrawn without incident. This rescue maneuver is crucial to prevent the loss of an unopened stent, especially in a coronary artery; otherwise, the patient's hemodynamic condition could deteriorate rapidly and death could ensue during the procedure.

As a stent is deployed by steadily increasing the inflation pressure to the expansion balloon, the diameter of the stent will slowly increase with expansion of its lumen. This causes a reduction in the length of the stent, which ordinarily occurs with any stent design, and which must be factored in to determine in advance whether sufficient coverage of injured tissue at he target site will be achieved using a single stent. According to the present invention, means are provided by which the stent undergoes an automatic controlled extension of its length to compensate for the shortening of its length that would ordinarily occur when its lumen diameter is expanded.

This is achieved by incorporating into the stent, elements which undergo a change that leads to a measured increase in the opposite direction. In the preferred embodiment, shown in FIG. **9**, the uniform longitudinal displacement of the circumferential sine wave-like patterns is interrupted at least once along the stent's axis by transversely oriented serpentine elements **70** that run longitudinally within the tube wall in juxtaposed at least partial sine wave-like patterns such as **71**, **72**, and that serve to shape openings such as **73** through the wall between them. Adjacent transverse patterns are offset from each other by a 180° cyclical phase difference at interconnecting points between them along the tube's axis, using the same analysis as was applied in the case of the circumferentially extending serpentines of FIG. **5**A. These transversely oriented serpentine elements are adapted to maintain the length of the tube substantially invariant with radial expansion of the stent. To that end, they are connected to adjacent points of the circumferential serpentines, as at **75** and **76**, but unconnected at their own crests (or troughs) so as not to constrain the diameter of the stent at those points.

This length-compensating effect may be seen by reference to analogous triangles of the diagrammatic representation in FIG. **10**, which may be used as a mathematical model for calculation. Triangles **70**, **79** represents related ones of the transverse and circumferential serpentines of FIG. **9**, connected at point **76**. As the short segment **88** of triangle **79** is extended (by a length **80**, consistent with the stent being expanded in deployment), so is the short segment **82** of triangle **70** (by a length **87**). The dimensions of the transverse serpentines relative to the cirumferential serpentines should be set such that length extension **87** matches the contraction of the length of segment **81** (corresponding to the long axis of circumferential serpentine **79**) to new length **81'**.

At a desired point in the fabrication of the stent of the invention, preferably after the openings **33** have been cut to form the serpentine structure and the electro machining has been performed, the stent may be polished to provide it with a taper **85** (FIG. **11**) of its outer diameter **86** by removing

sufficient material from the outside surface of the tube wall progressively from its mid-section **90** to each end **91, 92**. For example, the taper may be sufficiently pronounced to make the wall thickness 65 microns at each end, and a larger dimension in a range from 75 to 90 microns at the mid-section of the stent, with smoothly varying wall thickness. No change or only a small change is made in the inner diameter of the stent so that the lumen is unaffected. This longitudinal variation in outer diameter of the stent allows the stent to adapt itself to proper compliance with the vessel wall, with greater flexibility at the ends, without relinquishing the rigidity afforded through the mid-section of a tubular wall. As a result, bending stresses that would otherwise occur at the ends of the stent on the vessel wall, and which could produce restenosis, are considerably reduced. Preferably, the outer diameter of the stent at the ends is about 80–95% of the outer diameter at its mid-point.

Although a presently preferred embodiment and methods of the invention have been shown and described, it will be apparent to those skilled in the art from a consideration of the foregoing detailed description, that variations and modifications of the described embodiments and methods may be made without departing from the true spirit and scope of the invention. It is therefore desired that the invention be limited only by the following claims and the rules and principles of applicable law.

What is claimed is:

1. A vascular or endoluminal stent adapted to be expanded from a small diameter production state to a larger diameter deployed state for deployment in a vessel or tract of a patient to maintain an open lumen therein, said stent comprising a biocompatible hollow tube with a multiplicity of openings through an open-ended tubular wall thereof, said openings having a closed oval shape when said stent is in the production state, according to the shape of a plurality of serpentine elements bounding said openings within at least a substantial portion of said wall and running circumferentially in juxtaposed sine wave patterns, each of uniform multiple cycles, wherein adjacent ones of said patterns are offset 180 degrees out of phase from each other about the circumference of the tubular wall, are directly connected together without intervening bridges at the most closely confronting points of each pair of out of phase cycles of adjacent ones of the sine wave patterns, and are uniformly displaced longitudinally along an axis of the tube, said tube constituting a single member from which the entire stent is fabricated,

wherein the uniform longitudinal displacement of the circumferential substantially sine wave-like patterns is interrupted at least once along the axis of the stent by transversely oriented serpentine elements that run longitudinally within said wall in juxtaposed at least partial substantially sine wave-like patterns having openings through the wall which are shaped according to the transversely oriented serpentine elements, adjacent ones of the transverse patterns being offset from each other by a 180° cyclical phase difference at interconnecting points therebetween along the circumference of the tube, said transversely oriented serpentine elements being adapted to maintain the length of said tube substantially invariant with radial expansion of the stent.

2. A process for fabricating a vascular or endoluminal stent adapted for deployment in a vessel or tract of a patient to maintain an open lumen therein, comprising the step of laser cutting a biocompatible hollow tube to form a multiplicity of openings through an open-ended tubular wall thereof while simultaneously forming a plurality of serpentine elements in the wall running circumferentially therein in juxtaposed substantially sine wave patterns of uniform multiple wavelengths, with adjacent ones of said patterns tangentially contacting each other and interconnected directly at each point of tangential contact between waves thereof offset from each other by 180 degrees about the circumference of the tubular wall, said adjacent patterns arranged in uniform longitudinally displaced segments along the axis of the tube, whereby each of said openings in the wall deviates from a substantially oval shape only by virtue of notches formed at each side of the interconnection between waves at the respective points of tangential contact,

including the step of interrupting the longitudinal segments in which the substantially sine wave patterns are lying, at least once along the axis of the tube by laser cutting transversely oriented serpentine elements in the wall that run longitudinally in at least partial substantially sine wave patterns and juxtaposed circumferentially, while simultaneously cutting openings of said transversely oriented serpentine elements through the wall, and with adjacent ones of the transversely oriented patterns being offset from each other by 180° relative to their wavelengths at interconnecting points therebetween along the circumference of the tube, so that said transversely oriented serpentine elements will act to maintain the length of said tube substantially invariant with radial expansion of the stent.

3. A vascular or endoluminal stent adapted for deployment in a vessel or tract of a patient to maintain an open lumen therein, the stent comprising a metal open-ended tube having a multiplicity of through holes in the wall thereof, said tube being the single component of the stent with elements thereof being shaped throughout for optimizing symmetrical expansion of the stent without substantial deformation from a tubular shape during deployment thereof, the inner lumen of the tube being of uniform diameter throughout and the outer diameter of the tube ranging substantially uniformly from a maximum at the mid-point of the length of the tube to a minimum at each end of the tube whereby the tube wall is longitudinally tapered at the exterior surface thereof to be more flexible at its ends than at its mid-point.

4. A process for fabricating a vascular or endoluminal stent adapted for deployment in a vessel or tract of a patient to maintain an open lumen therein, comprising the steps of forming a multiplicity of generally oval-shaped openings through an open-ended tubular wall of a biocompatible hollow tube, to leave a multiplicity of interconnected serpentine elements bounding the openings and maintaining the tubular shape of the wall, tapering the outer surface of the wall to be thicker from the middle of the length to each thinner end thereof while maintaining a uniform diameter throughout the lumen of the tube, so as to render the stent more rigid in the middle and more flexible at the ends thereof.

* * * * *

EXHIBIT C.

LPL Systems, Inc.

Customer: Tim Lamone
Giudant

Quote No:11295
Date:11/29/95

System Description

ITEM	DESCRIPTION	COST
1	(1) LPL 105 Laser Stent Cutting System	

SYSTEM INCLUDES:
Lasag KLS 126 YAG Laser or equivalent.
YAG Beam Delivery System
Including:
Cutting Nozzle independently adjustable
from final focusing lens.
4 inch focal length lens
Video System and Monitor.
High Intensity Fiber Optic Illuminator.
Crossline Generator.

High precision X/Y motion system, including:
Servo controlled 6 inch travel X stage
.1 Mill Resolution.
Servo controlled 6 inch travel y stage
.1 Mill Resolution

High Precision Rotary Stages,
with the following specifications:
Resolution - .02 Degrees
Max. Speed - 60 RPM
Accuracy - +/- .0044 Degrees.
Repeatability - .02 Degrees

Stent Cutting Tooling, including:
Pneumatically Activated Collets (3 Sizes)
Tubing Length Capacity - 24 Inches
Max. Length of Stent - 5 Inches
Max. Diameter of Tubing - .3 inches
Automatic Programmable Tube Feeder
Multiple cutting support gases, program
selectable.

3 Axis CNC controller
with linear and circular interpolation.
controls for manual Jogging.

250 Polaris Avenue
Mountain View, CA 94043

Phone:
(415) 965-9884

Fax:
(415) 965-9481

Digital I/O Interface
Cad/Cam Program
CAD postprocessor.
Floppy Disk Drive
Laser Fire Control Card

486 PC Computer.
3 Axis of Servo Amplifiers and motor/tach/encoders.
(6000 RPM Rated)
Welded System Frame, including:
Shock isolated Subframe for Lasers and Motion System.
Sheet Metal Enclosure.
CDRH Safety Interlocks.
Rack Mount for Computer and Electronics.

System Price $ 343,830. ea

FOB: Mtn. View CA.

Terms: 40% Downpayment with order.
30% Upon Shipment
30% Upon Acceptance.

Warranty: 12 months from date of installation

Please Note: This System is designed to cut Stents from tubing stock using a proprietary cutting method and post laser cutting process technology. Production rates are 6 to 10 stents per hour, based on a 10mm stent, .060 O.D. and a 4 mill wall thickness. Typical production accuracies of stents are +/-.5 Mills on all dimensions.
This cutting technology does not require so called " Gates" the stent are cut from tubing (36 inches/load) and collected in tray ready for postprocessing.

EUROPEAN PATENT OFFICE,
Erhardtstrasse 27,
D-80331 MUNICH,
GERMANY

DECLARATION OF CHARLES A. TAYLOR

I, Charles A. Taylor declare as follows:

1. I am a professor in the Departments of Surgery, Mechanical Engineering and Pediatrics at Stanford University. I have a B.S. and M.S. in Mechanical Engineering from Rensselaer Polytechnic Institute, an M.S. in Mathematics from Rensselaer Polytechnic Institute, and a Ph. D in mechanical engineering from Stanford University. My resume is attached as Exhibit 1 of this declaration.

2. I have reviewed PCT publication PCT/US95/08975, entitled "A Flexible Expandable Stent" (which I am told is document 'D1' in these proceedings).

3. The stent design shown in Figures 1 through 4 has sharp corners that cause stress concentration, as would be recognized by one of skill in the art. It is basic engineering knowledge that concentration of stresses in a load-bearing device is undesirable, and especially so in a medical device such as a stent that is implanted in the human body.

4. The concept of stress concentrations at corners and other changes in cross-section is well-documented in standard mechanical engineering textbooks, examples of which are Exhibit 2 to this declaration. Stent design must take account of the distribution of stress due to the ongoing loads that the devices are subject to by the flow of pumping blood under cyclic pressure, motion of organs and natural body movements. Coronary stents are subject to repeated stresses, as the human heart beats approximately 100,000 times per day, or 40 million per year.

5. If a skilled person wanted to make the stent shown in Figures 1 through 4, it would be a routine manufacturing choice to reduce the stress concentrations by introducing some curve to the right-angle bends. This would be obvious to someone looking at Figures 1 through 4 and is further supported by reading the specification that accompanies those figures. For example, the specification repeatedly describes the stent design as having a meandering pattern consisting of "loops" and it is specifically stated that the meander pattern 11 (shown e.g. in figures 1-4) is a "vertical sinusoid" (see page 4, lines 20-29). The specification also suggests that the pattern of Figure 2 can be manufactured of welded or twisted wire (page 7, lines 24-25.) If the pattern shown in Figure 2 was made of twisted wire, it would be physically impossible to make sharp corners, but a skilled person would round the corners, as dictated by the properties of wire.

6. A person of skill in the art seeking to make the stent shown in Figures 1 through 4 would take particular care to make the loops of Figures 1 through 4 rounded to prevent any sharp corners from injuring the inner surface of an artery upon bending of the stent, including the bending which such stents will encounter as they navigate the artery (or other lumen) during delivery, expansion and in use. It is well known to a person skilled in the art of designing stents that injury to a blood vessel resulting from sharp corners could result in intimal thickening and restenosis. This concept is well-recognized, as shown in U.S. Patent No. 5,192,307 (which is Exhibit 3 to this declaration) at col. 5, lines 37 - 45: "*While several designs and materials have been disclosed, those skilled in the art will recognize that the materials must be implantable, and all portions of the stent must be sufficiently smooth to prevent trauma during placement. Further, all corners and the like should be well rounded to prevent epithelialization without subsequent trauma due to the presence of sharp edges during natural body motions.*" It was elementary knowledge that devices with sharp edges should not be implanted into patients at least as early as 1993.

7. For all these reasons it is clear that were a skilled person to seek to make the device as shown in Figures 1 through 4 they would make a device with a curved pattern, not one with square corners as shown.

8. I have reviewed EP 1 066 804 B1, and specifically the portion appearing at column 7, lines 7-15 , which describes the supposed advantages of having flat apices.

9. The first supposed advantage given is that the flat apices will result in "the force required to expand the stent is substantially reduced." I disagree with this statement. In fact, there is no inherent advantage to using a flat apex such as that shown in the figures of the EP 1 066 804 B1 patent. My opinion in this regard is supported by a finite element analysis performed to evaluate this point.

10. A finite element analysis is a numerical solution to the equations governing the deformation of solid objects subject to applied loads - as occurs when a stent is expanded into a diseased artery. These governing equations, based on the laws of physics, cannot be solved without such methods for the complex geometry and material behavior intrinsic to stent deployment. The finite element analyses performed involved deforming varying stent geometries and calculating the force required to expand the stent and the resulting stresses and plastic deformation.

11. A finite element analysis was performed comparing a design as shown in EP 1 066 804 B1 with two modifications. In the first modification, a series of apices were changed from flat by creating a "dimple" ("Modification 1"). In the second modification, a different series of apices were changed from flat by being rounded into a curved shape ("Modification 2"). The analysis is attached hereto as Exhibit 4.

12. The finite element analysis demonstrates that in both modifications there is no advantage in using flat apices in terms of reduced force required to expand the stent, as claimed in the patent. The expansion force is essentially unchanged when the apices are changed from flat to either curved or dimpled in modifications. Those results are shown in the accompanying graph and Table 1 in Exhibit 4.

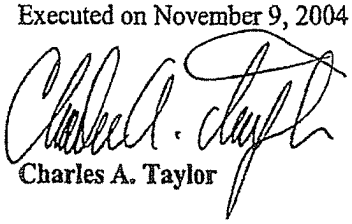
13. The second supposed advantage provided is that the stent is subjected to less traumatic stress during expansion with the use of flat apices. I disagree with this statement as well. The finite element analysis further supports this point.

14. The finite element analysis illustrates that in Modification 2 there is actually lower maximum stress and strain (and thus lower traumatic stress) in the modified curved apex as compared to that obtained with flat apices. The analysis further indicates that in Modification 1 there is lower maximum stress or strain (and thus lower traumatic stress) in the modified "dimpled" apex as compared to that obtained with flat apices. These results are shown in Tables 2 and 3 in Exhibit 4. Further, the flat apices actually cause higher localized stress (and thus maximum stress), as can be seen in the stress fields illustrated in Exhibit 4.

15. The patent also claims as an advantage that the use of flat apices facilitates the plastic deformation of the stent during expansion. I also disagree with this statement. The finite element analysis demonstrates that there is no advantage to using flat apices in this regard, because the expansion of the stent (and necessary deformation) is not facilitated by the use of flat apices.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on November 9, 2004 at Stanford, California.



Charles A. Taylor

EXHIBIT 1

Exhibit 1

Charles A. Taylor, Ph.D.

A. Identifying data:

1. Date of birth; place of birth: 1/3/64; Fall River, MA
2. Citizenship status: US Citizen

B. Academic history:

1. Colleges and universities attended, degrees received, and dates

1996	Ph.D.	Mechanical Engineering	Stanford University
1992	M.S.	Mathematics	Rensselaer Polytechnic Institute
1991	M.S.	Mechanical Engineering	Rensselaer Polytechnic Institute
1987	B.S.	Mechanical Engineering	Rensselaer Polytechnic Institute

C. Employment history:

4/01 - present Assistant Professor, Department of Mechanical Engineering, Stanford University

4/01 - present Assistant Professor, Department of Surgery, Stanford University

10/02 - present Assistant Professor (by courtesy), Department of Pediatrics, Stanford University

7/97 – 4/01 Assistant Professor (Research), Department of Surgery, Stanford University

7/97 – 4/01 Assistant Professor (Research), by courtesy, Department of Mechanical Engineering, Stanford University

1996 - 1997 Engineering Research Associate, Department of Surgery, Stanford University

1994 - 1996 Research Assistant, Department of Mechanical Engineering and Department of Surgery, Stanford University

1992 - 1994 Research Assistant, Department of Mechanical Engineering, Stanford University

1991 - 1992 Teaching Assistant, Department of Mathematics, Rensselaer Polytechnic Institute

1987 - 1991 Mechanical Engineer, Engineering Physics Laboratory, GE Research & Development and Materials Divisions

D. Public and Professional Service:

National and International Committees

Chair, Session on Fluid Mechanics - Flow Visualization & Virtual Reality, 1998 ASME Winter Annual Meeting, Anaheim, CA.

Chair, Symposium on Computational Bioengineering, 1999 ASME Summer Bioengineering Mtg., Big Sky, MT.

Chair, Session on Computer-Aided Surgical Simulation and Planning, 1999 ASME Summer Bioengineering Mtg., Big Sky, MT.

Chair, Session on Visualization, VR and Image-Based Computational Techniques, 1999 ASME Summer Bioengineering Mtg., Big Sky, MT.

Chair, Session on Experimental and Computational Investigations in Bioengineering, 1999 ASME Summer Bioengineering Mtg., Big Sky, MT.

Chair, Session on Image Registration and Fusion, 1999 BMES/EMBS Mtg., Atlanta, GA.

Chair, Session on Cardiovascular Fluid Dynamics, 2000 World Congress of Medical Physics and Biomedical Engineering, Chicago, IL.

Chair, Session on Cardiovascular Flow and Hemodynamics, 2000 World Congress of Medical Physics and Biomedical Engineering, Chicago, IL.

Chair, Session on Medical Imaging and Registration, 2000 Computer Aided Radiology and Surgery, San Francisco, CA.

Chair, Session on Computational Biomechanics, 2001 ASME Summer Bioengineering Mtg., Snowbird, UT.

Member, Organizing Committee, 2000 Computer Aided Radiology and Surgery, San Francisco, CA.

Member, Biofluids Committee, ASME.

Member, Scientific Committee, 2003 CalTech Biofluids Conference

Chair, Symposium on Computational Methods in Cardiovascular Bioengineering, 2004 World Congress on Computational Mechanics, International Association for Computational Mechanics, Beijing, China.

Member, Scientific Advisory Board, Third M.I.T. Conference on Computational Fluid and Solid Mechanics, June 14 - 17, 2005

Member, Scientific Committee, 8th National Congress on Computational Mechanics (USNCCM8), Austin, TX, Austin, Texas, July 24 - July 28, 2005

Grant Review Panels

Member, Biomedical Engineering Review Panel, National Science Foundation, June 2000.

Member, Biomedical Information Science and Technology Review Panel, National Institutes of Health, July 12-13, 2001, November 1-2, 2001.

Member, American Heart Association, Western States Affiliates, Peer Review Panel, April 10-11, 2003, April 20-21, 2004.

Journal Editorial Boards, Review

Advisory Editorial Board, Journal for Multiscale Computational Engineering

Ad-hoc Reviewer, ASME Journal of Biomechanical Engineering, Journal of Vascular Surgery, Annals of Biomedical Engineering, Arteriosclerosis, Circulation, Applied Numerical Mathematics, Computer Methods in Applied Mechanics and Engineering, IEEE Transactions on Visualization and Computer Graphics, IEEE Transactions on Medical Imaging, IEEE Transactions on Biomedical Engineering, Journal of Fluid Mechanics, Journal of Biomechanics.

Professional Organizations

Biomedical Engineering Society, American Society of Mechanical Engineers, International Society for Magnetic Resonance in Medicine, American Mathematical Society, Society for Industrial and Applied Mathematics, American Academy of Sciences.

Stanford Committees

Mechanical Engineering Department Vision Committee, 1997-1998.

Medicine Meets Virtual Reality at Stanford Organizing Committee, September 1998-January 1999.

Biomedical Information Technology at Stanford (BITS) committee, founding member, March 1999-present.

Clark Center, Design and Planning Committee, November 1999-May 2000.

iBME Leadership Committee, March 2000-December 2000.
Stanford Medical Device Network Leadership Group, 1998-2002.
Surgery Department Space Planning Committee, March, 2000-December 2000.
Bio-X Core Facility in Biocomputation oversight committee, Chair, July 2000–present.
Mechanical Engineering Department Undergraduate Committee, September 2001–present.
Bioengineering Department Planning Committee, January 2002–June, 2002.
Bioengineering Undergraduate curriculum committee, Co-chair, January, 2002–June, 2002.
Bioengineering Department Chair Search Committee, July 2002–Sept 2002.
Biodesign Program Research Committee, Chair, July 2002–Sept 2004.
Medical School Bioengineering Scholarly Concentration, Co-director, August 2003–present.
ICME Curriculum Committee, October 2003-present.
Stanford Research Supercomputing Committee, September 2004-present.

E. Post-Degree Honors and Awards:

National and International Awards

Young Investigator in Computational Mechanics Award, International Association for Computational Mechanics, 2002.

R.H. Gallagher Young Investigator in Computational Mechanics Award, U.S. Association for Computational Mechanics, 2003.

Stanford University Awards

James F. Clark Fellow, Stanford University, 2001.

Keynote and Plenary Lectures

Distinguished Lecturer, 1998 International Symposium on Computational Medicine, Tokyo, Japan.
Keynote Speaker, Virtual Reality Session, 1999 High Performance Computing and Networking Conference, Amsterdam, The Netherlands.
Keynote Speaker, 1st Annual Symposium for The Centre for Vascular Imaging Research on Virtual Reality in Vascular Medicine (1999), The John P. Robarts Research Institute, London, Ontario, Canada.
Keynote Speaker, Bioengineering Session, 2000 Applied Mathematics in Industrial Flows Conference, Tuscany, Italy.
Keynote Speaker, First International Symposium on Advanced Fluid Information, 2001, Sendai Japan.
Keynote Speaker, Taiwan National Computational Fluid Dynamics conference, 2002, Tainan, Taiwan.
Keynote Speaker, United States Association for Computational Mechanics conference, Albuquerque, NM, July 2003.
Keynote Speaker, Computational Sciences Symposium, Trondheim, Norway, October 2003.
Keynote Speaker, San Francisco Surgical Society Meeting, San Francisco, CA, October 2003.
Distinguished Speaker, Red-Raider Mini-Symposium on Mathematical and Computational Modeling of Biological Systems, Lubbock, TX, November 2003.
Keynote Speaker, International Symposium on Biomedical Systems Innovation, Tokyo, December 2004.
Plenary Speaker, Society of Industrial and Applied Mathematics annual meeting, New Orleans, LA, July 2005.

Magazines, Television and Radio

Beyond 2000, Segment on "Virtual Circulatory System", aired September, 1999 on Discover Channel.

The Osgood Files, Segment on "Virtual Circulatory System", aired on CBS Radio Network, June, 1999.
New Media News, Segment on "Stanford Virtual Surgery", aired November 21, 1999.
Quantum, Segment on research program, aired on Australian Broadcasting Corporation TV on Thursday 24 February, 2000.
Discover Magazine, Article entitled "Downloading Your Body", Sept. 2000, pp. 83-85.
Mechanical Engineering Magazine, Article entitled "High Tech Healing", January 2001, pp. 62-65.
Stanford Medicine Magazine, Article entitled "The MRI workout: A customized cycle provides blood-flow data", Volume 20, #1, Winter 2003, pp. 20 and 23.
Technology Review Magazine, Article entitled "Simulating Surgery", March 2003, p. 26.
The Scientist, Featured in article "The Democratization of Supercomputing" Aug. 30, 2004, pp. 30-33.

Scientific Exhibits

San Francisco Exploratorium, Blood flow simulations in human aorta, part of exhibit on "Revealing Bodies", March 2000–September 2000.

The Tech Museum of Innovation, San Jose, Cardiovascular Surgery Planning demonstrations in VR Theatre, June 21, 2003.

F. Teaching:

1. E 155A Mathematical and Computational Methods for Engineers, Stanford University, 2004.
2. ME 184/284 Cardiovascular Bioengineering, Stanford University 2002, 2003, 2004.
3. ME 484 Computational Methods in Cardiovascular Bioengineering, Stanford University 2002, 2003.
4. ME 184/284 Cardiovascular Biomechanics, Stanford University 1998, 1999, 2000, 2001.
5. ME 234C Finite Element Methods in Fluid Mechanics, Stanford University 1999.
6. ME 235C Finite Element Methods, Stanford University 2000.
7. ME 232A,B,C Simulation-Based Design & Computational Prototyping, Stanford Univ. 1996-97.
8. ME 289 Medical Device Forum (Seminar, w/ P. Yock, M.D.), Stanford University 1999, 2000.
9. ME 288 Bioengineering & Biodesign (Seminar, w/ P. Yock, M.D.), Stanford University 2001, 2002.
10. "The Cardiovascular System in Health and Disease: Fundamental Concepts for the Medical Device Industry" (Stanford Short Course), September 19-21, 2001, June 19-21, 2002, June 11-13, 2003, June 15-18, 2004 (4 Years consecutively). Course developer, director, and primary lecturer.
11. "Finite Element Modeling of Cardiovascular Devices", Short course taught at the Center for Devices and Radiological Health, Food and Drug Administration, September 15-16, 2004.

G. Scholarly Publications:

Peer Reviewed Papers (students indicated in boldface)

1. H.F. Nied, C.A. Taylor, and H.G. deLorenzi, (1990) Three Dimensional Finite Element Simulation of Thermoforming. *Polymer Engineering and Science*, Vol. 30, No. 20, pp. 1314-1322.
2. H.G. deLorenzi, H.F. Nied, C.A. Taylor, (1991) A Numerical/Experimental Approach to Software Development for Thermoforming Simulations. *ASME Journal of Pressure Vessel Technology*, Vol. 113, pp. 102-114.
3. C.A. Taylor, H.G. deLorenzi, and D.O. Kazmer, (1992) Experimental and Numerical Investigations of the Vacuum forming Process. *Polymer Engineering and Science*, Vol. 32, No. 16, pp. 1163-1173.
4. H.G. deLorenzi, and C.A. Taylor, (1993) The Role of Process Parameters in Blow Molding and Correlation of 3-D Finite Element Analysis with Experiment. *International Polymer Processing*, Vol. VIII, No. 4, pp. 365-374.
5. J.C. Simo, F.A. Armero, and C.A. Taylor, (1995) Stable and Time-Dissipative Finite Element Methods for the Incompressible Navier-Stokes Equations. *International Journal for Numerical Methods in Engineering*, Vol. 38, pp. 1475-1506.
6. C.A. Taylor, T.J.R. Hughes, and C.K. Zarins, (1996) Computational Investigations in Vascular Disease. Computers in Physics, Vol. 10, No. 3, pp. 224-232.
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EXHIBIT 2

STRENGTH OF MATERIALS

A FIRST COURSE

By

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PREFACE

This text is the outgrowth of *Strength of Materials* published by the author in 1938, jointly with the late Professor N. C. Riggs. Except for the chapter on "Columns and Curved Beams," the book has been rewritten and rearranged.

The first three chapters contain what is believed to be a new and simpler approach to the teaching of a first course in strength of materials. The essential aspect of this approach lies in starting the course with statically determinate problems in stress analysis. It is surprising how many good approximations to practical problems can be obtained by the laws of statics alone without the use of stress-strain relations.

The first chapter deals with fundamental concepts. It opens with a discussion of the basic types of failure, the prevention of which becomes the primary objective of the course. It describes the mechanical properties essential to the understanding of failure and establishes the fundamental concepts of stresses and their distribution.

Chapters 2 and 3 deal with statically determinate problems in tension, compression, bending, and torsion. Stresses are calculated in uniform bars under axial loads, in flange-type beams, and in thin-walled circular cylinders. The solutions are effected by means of the laws of statics alone and the primary emphasis is on the methods of procedure.

Using superposition, the student is next made acquainted with two-dimensional stress systems such as those developed in circular tubes subjected to the combined action of axial loads, internal pressure, and pure torsion.

The first three chapters will be found to provide a preview of the main stress problems to follow, as well as of basic principles and methods. They show the scope of the subject and the place of statics in stress analysis. This approach to stress analysis via the route of statically determinate problems, coupled with the emphasis on the significance of the stresses, has been found by the author to provide a direct link with statics and an effective entrance into the study of strength of materials.

Basic concepts of strain and their first fundamental applications are introduced in Chapter 4. The student is now prepared to understand and to be interested in a study of stresses and strains at a point, a subject of critical importance. This topic is treated in detail in Chapter 5.

Following a concise statement of the three basic problems regarding stresses at a point, the solutions are first effected analytically and next graphically. The analysis of stresses is followed by a parallel analysis

Find the maximum tension at the wall and the shear flow on the horizontal plane of symmetry.

2-35. In Fig. 2-22 let the distance between the planes B-B and B'-B' be Δx. Prove that the limit $dM/dx = R - P$.

Part III. Stress Concentrations

2-9. Stress Concentrations. We consider again stresses produced by axial loads in long bars of uniform cross section. It is known that in such cases the transverse section of symmetry and the adjacent regions are in a state of uniform stress. However, when axial loads act on bars

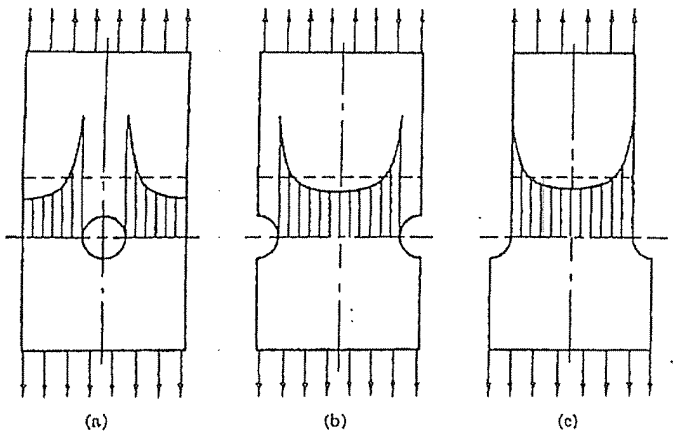

FIG. 2-36.

which contain a sudden change in shape, such as produced by a hole, grooves, or fillets, Fig. 2-36, the stresses are no longer uniform, but follow approximately the distributions shown.

A sudden change in shape, or discontinuity, gives rise to a sharp local increase in the boundary stresses, which is generally called a *stress concentration*. For example, a central circular hole, Fig. 2-36(a), develops high local stresses on the boundary of the hole. Similarly, grooves and fillets produce high stresses on the curved boundaries, Figs. 2-36(b) and (c).

The ratio P/A represents the true stress only in long uniform bars. Where the sections of the bars are not uniform and discontinuities exist, the ratio P/A represents only the mean or average stress, which may

differ radically from the true maximum stress on the section. The presence of stress concentrations is clearly shown in Fig. 4-4. For the time being, we are not concerned with the significance of the maximum stresses or the adequacy of the mean stresses in design problems. Here we are concerned with factual aspects. A clear knowledge of the existence of stress concentration must precede the evaluation of their technical significance.

In general, stress concentrations are of primary significance in machine design and of much lesser importance in structural analysis. This topic is further discussed in Chapter 9.

2-10. Factors of Stress Concentrations. When the stresses at a section are not uniform, the maximum stress may be determined by advanced analytical or experimental methods. In plane stress problems

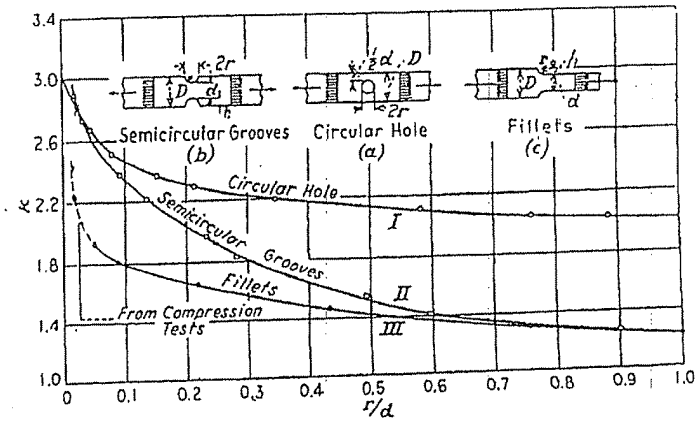

FIG. 2-37. Factors of stress concentration for circular holes, semicircular grooves, and fillets of depth equal to the radius ($h/r = 1.00$) in fields of pure tension or compression.[3]

of complicated shapes the maximum stresses are generally determined photoelastically (see Arts. 6-8 to 6-12). It has been found convenient to express the maximum stress as a linear function of the nominal stress which, for axial loads, is P/A. Thus we write

$$\sigma_{max} = K\sigma_{nom} \tag{2-13a}$$

[3] Figs. 2-37, 2-40, 2-41, and 2-42 are from the author's paper "Photoelastic Studies in Stress Concentrations" which appeared in *Mechanical Engineering, Journal* of the A.S.M.E., August, 1936.

The constant k is called the *factor of stress concentration*. From Eq. (2–13a)

$$k = \frac{\text{maximum stress at a given section}}{\text{nominal stress at the same section}} \qquad (2\text{–}13b)$$

Three curves of k are shown in Fig. 2–37. Curve I is for circular holes, curve II is for semicircular grooves and curve III is for fillets. The factors k defined by Eq. (2–13b) may be viewed as correction factors to be applied to the stresses at a section calculated on the assumption of uniform distribution.

Some writers define the factor of stress concentration by the expression

$$k = \frac{\text{maximum stress at a specified section}}{\text{nominal stress at some other section}} \qquad (2\text{–}14)$$

For example, in a straight bar with a hole they would calculate the nominal stress not at the section through the hole but at a section in the solid portion of the bar. This would of course yield a different value for k than that given by Eq. (2–13b).

It is thus seen that the value of k depends on the definition of the nominal stress. The curves in Fig. 2–37 as well as other curves of k given in this book are based on Eq. (2–13a), in which s_{max} and s_{nom} refer to one section. This method is generally used by photoelasticians.

2–11. Factors Influencing Stress Concentrations. The curves of Fig. 2–37 clearly show that the factors of stress concentration depend on the shape of the discontinuity in the bar. Specifically, for $r/d = 0.2$ the factor k equals 2.3 for a circular hole, 2.04 for semicircular grooves and only 1.65 approximately for fillets. Similar effects exist at other values of r/d.

The factors of stress concentrations, as here defined, depend solely on the geometry of the specimen and the manner in which the loads are applied. They do not depend on the absolute dimensions or magnitudes of the loads. A striking illustration of the influence of the shape or geometry upon the stresses is shown in Fig. 2–38. It can be shown that in both bars the longitudinal tensile stresses s_x are accompanied by transverse stresses s_y. However, in the grooved bar, s_y is tensile whereas in the bulged bar, s_y is compressive.

2–12. Effect of Yielding on the Stress Distribution. The property of mild steel to increase its strain without an appreciable increase in stress, i.e., to yield, has a pronounced effect on the stress distribution actually existing at failure. Fig. 2–39 shows the change in the stress distribution in an aluminum bar containing a small hole when strained beyond the yield point. From this it follows that under static conditions the stress distribution in mild steel, and similar ductile materials, tends to approach

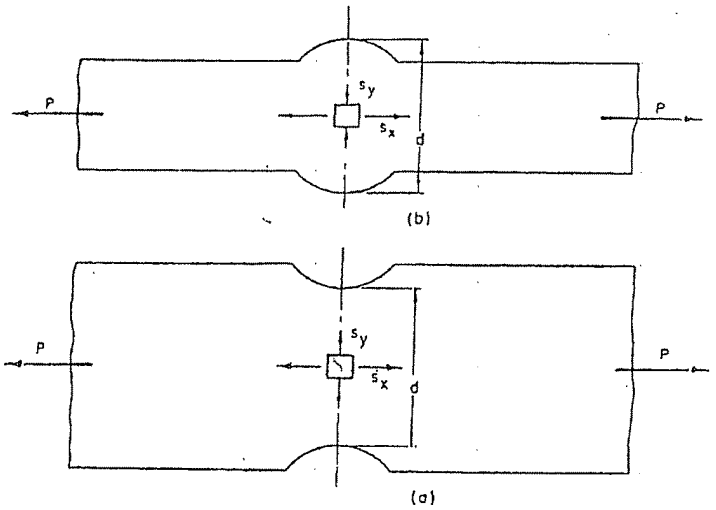

FIG. 2–38.

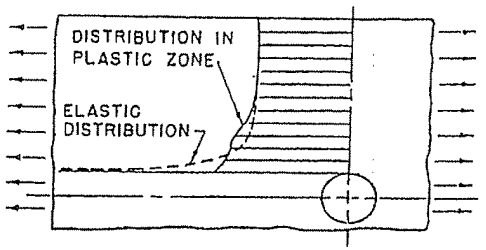

FIG. 2–39.

uniformity at failure. This, however, is not true in brittle materials or for that matter in ductile materials under conditions of fatigue.

Figs. 2–40, 2–41, 2–42 contain additional factors of stress concentration for bars in tension or compression.

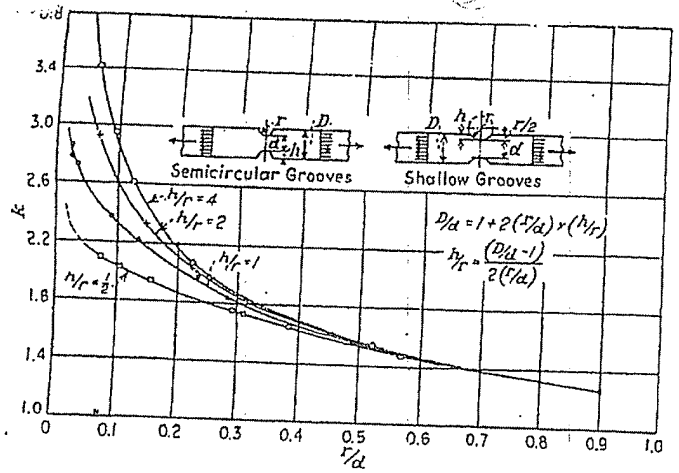

FIG. 2-40. Factors of stress concentration for deep and shallow grooves in tension or compression.[1] $\sigma_m = k(P/A)$

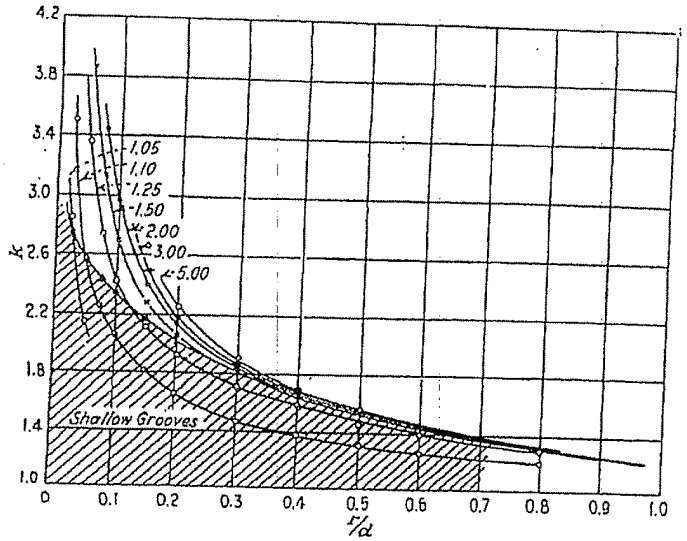

FIG. 2-41. Factors of stress concentration for deep and shallow grooves in tension or compression.[1] Factors of stress concentration (k) plotted against r/d for various values of D/d.

[1] *Ibid.*

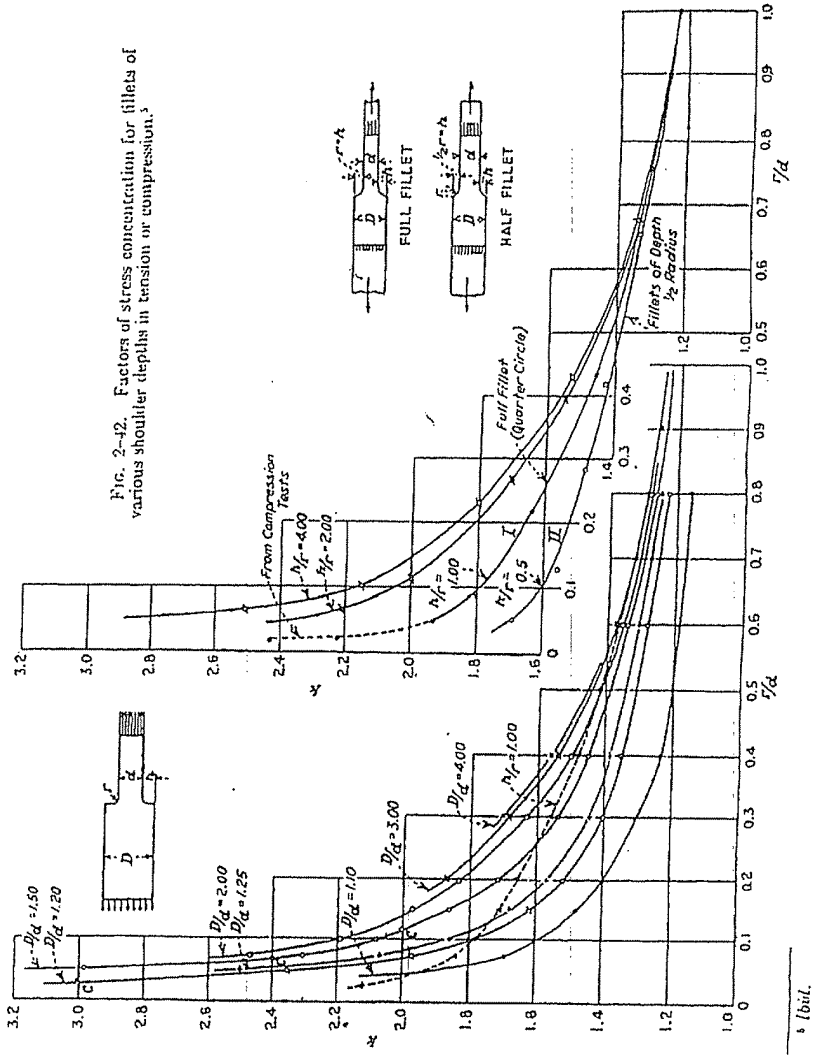

FIG. 2-42. Factors of stress concentration for fillets of various shoulder depths in tension or compression.[1]

[1] *Ibid.*

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Eighth Edition

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The editors and the publishers will be grateful to readers who notify them of any inaccuracy or important omission in this book

(continued on back flap)

Preface to the Eighth Edition

In the preparation of the eighth edition of "Marks," the editors had several major objectives. First, to modernize and update the contents as required; second, to introduce the SI system of units where applicable; and third, to recast the Handbook into a two-column format to enhance the visual presentation of textual matter and thereby increase its readability and usefulness.

It is recognized that, at this time, the U. S. Customary System (USCS) of units cannot be completely replaced by the International System (SI). A transition from USCS to SI will proceed at a rational pace to accommodate the needs of the profession, of industry, of the polity, and of the citizenry. The transition period most likely will be long and complex, and duality of units probably will be demanded for several decades. Incorporation of dual units to the maximum extent possible will make the eighth edition useful for many years to professional engineers and to students.

Established practices and new concepts are the warp and woof which not only constitute the fabric of the profession, but also serve to keep it alive and progressive. For example, increased recognition of the social implications of engineering has resulted in a new section on environmental control.

The editors were cognizant of the competing requirements to offer the user the broad spectrum of information that has made the Handbook so useful for over sixty years, and yet to keep the size of the one volume within reason. This was achieved through the enthusiastic and timely cooperation of contributors, reviewers, and publisher.

Last, the Handbook is ultimately the responsibility of the editors. Meticulous care has been exercised to avoid errors, but, if any are inadvertently included, the editors will appreciate being informed so that they may be eliminated from subsequent printings of this edition.

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THEODORE BAUMEISTER
EUGENE A. AVALLONE
THEODORE BAUMEISTER III

Preface to the First Edition*

This Handbook is intended to supply both the practicing engineer and the student with a reference work which is authoritative in character and which covers the field of mechanical engineering in a comprehensive manner. It is no longer possible for a single individual or a small group of individuals to have so intimate an acquaintance with any major division of engineering as is necessary if critical judgment is to be exercised in the statement of current practice and the selection of engineering data. Only by the co-operation of a considerable number of specialists is it possible to obtain the desirable degree of reliability. This Handbook represents the work of fifty specialists.

Each contributor is to be regarded as responsible for the accuracy of his section. The number of contributors required to ensure sufficiently specialized knowledge for all the topics treated is necessarily large. It was found desirable to enlist the services of thirteen specialists for an adequate handling of the "Properties of Engineering Materials." Such topics as "Automobiles," "Aeronautics," "Illumination," "Patent Law," "Cost Accounting," "Industrial Buildings," "Corrosion," "Air Conditioning," "Fire Protection," "Prevention of Accidents," etc., though occupying relatively small spaces in the book, demanded each a separate writer.

A number of the contributions which deal with engineering practice, after examination by the Editor-in-Chief, were submitted by him to one or more specialists for criticism and suggestions. Their co-operation has proved of great value in securing greater accuracy and in ensuring that the subject matter does not embody solely the practice of one individual but is truly representative.

An accuracy of four significant figures has been assumed as the desirable limit; figures in excess of this number have been deleted, except in special cases. In the mathematical tables only four significant figures have been kept.

The Editor-in-Chief desires to express here his appreciation of the spirit of co-operation shown by the Contributors and of their patience in submitting to modifications of their sections. He wishes also to thank the Publishers for giving him complete freedom and hearty assistance in all matters relating to the book from the choice of contributors to the details of typography.

Cambridge, Mass.
April 23, 1916

LIONEL S. MARKS

*Excerpt.

condition promotes brittle fracture. On the other hand, ductility is enhanced and fracture is suppressed by triaxial compression.

Stress Concentration In a structure or machine part having a notch or any abrupt change in cross section, the maximum stress will occur at this location and will be greater than the stress calculated by elementary formulas based upon simplified assumptions as to the stress distribution. The ratio of this maximum stress to the nominal stress (calculated by the elementary formulas) is the stress-concentration factor K_t. This is a constant for the particular shape and is independent of the material, provided it is isotropic. The stress-concentration factor may be determined experimentally or, in many cases, theoretically from the mathematical theory of elasticity. The factors shown in Figs. 6 to 13 were determined from both

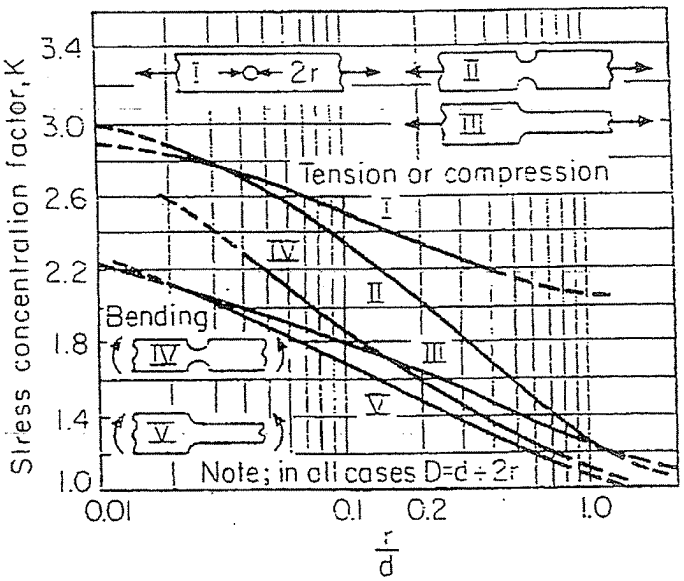

Fig. 6 Flat plate with semicircular fillets and grooves or with holes, in tension or compression.

photoelastic tests and the theory of elasticity. Stress concentration will cause failure of brittle materials if the concentrated stress is larger than the ultimate strength of the material. In ductile materials, concentrated stresses higher than the yield strength will generally cause local plastic deformation and redistribution of stresses (rendering them more uniform). On the other hand, even with ductile materials areas of stress concentration are possible sites for fatigue if the component is cyclically loaded.

made by the distortion-energy theory, according to which the criterion is

$$(\sigma_1 - \sigma_2)^2 + (\sigma_2 - \sigma_3)^2 + (\sigma_3 - \sigma_1)^2 = 2(\sigma_{ys})^2$$

Stress-strain curves in the plastic region for combined stress loading can be constructed. However, a particular stress state does not determine a unique strain value. The latter will depend on the stress-state path which is followed.

Plane strain is a condition where strain is confined to two dimensions. There is generally stress in the third direction, but because of mechanical constraints, strain in this dimension is prevented. Plane strain occurs in certain metalworking operations. It can also occur in the neighborhood of a crack tip in a tensile loaded member if the member is sufficiently thick. The material at the crack tip is then in triaxial tension, which condition promotes brittle fracture. On the other hand, ductility is enhanced and fracture is suppressed by triaxial compression.

Stress Concentration In a structure or machine part having a notch or any abrupt change in cross section, the maximum stress will occur at this location and will be greater than the stress calculated by elementary formulas based upon simplified assumptions as to the stress distribution. The ratio of this maximum stress to the nominal stress (calculated by the elementary formulas) is the stress-concentration factor K_t. This is a constant for the particular shape and is independent of the material, provided it is isotropic. The stress-concentration factor may be determined experimentally or, in many cases, theoretically from the mathematical theory of elasticity. The factors shown in Figs. 6 to 11 were determined from both

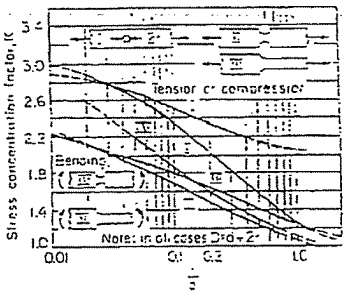

Fig. 6 Flat plate with semicircular fillets and grooves or with holes, in tension or compression

photoelastic tests and the theory of elasticity. Stress concentration will cause failure of brittle materials if the concentrated stress is larger than the ultimate strength of the material. In ductile materials, concentrated stresses higher than the yield strength will generally cause local plastic deformation and redistribution of stresses (rendering them more uniform). On the other hand, even with ductile materials areas of stress concentration are possible sites for fatigue if the component is cyclically loaded.

FRACTURE AT LOW STRESSES

Materials under tension sometimes fail by rapid fracture at stresses much below their strength level as determined in tests

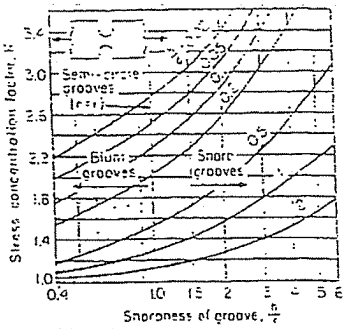

Fig. 7 Flat plate with grooves, in tension

on carefully prepared specimens. These brittle, unstable, or catastrophic failures originate at preexisting stress-concentrating flaws which may be inherent in a material.

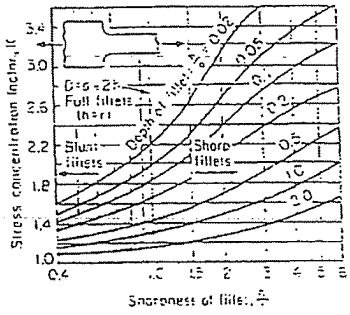

Fig. 8 Flat plate with fillets, in tension

The transition-temperature approach is often used to ensure fracture-safe design in structural-grade steels. These materials exhibit a characteristic temperature, known as the ductile brittle transition (DBT) temperature, below which they are susceptible to brittle fracture. The transition-temperature approach to fracture-safe design ensures that the transition temperature of a material selected for a particular application is suitably

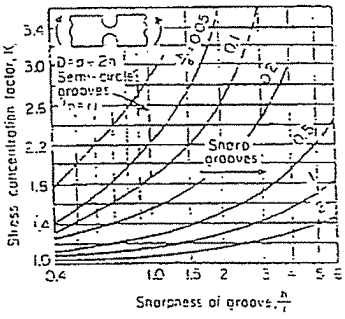

Fig. 9 Flat plate with grooves, in bending

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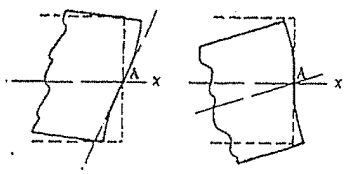

FIG. 49.

Figure 51 illustrates the distribution of stresses down into the solid for the case of two cylinders made from the same material, for which the contact patch is a long thin rectangle. Note that the highest shear stress is τ_{yz} which has a maximum value of about $0{\cdot}3\,p_0$ at a depth of some $0{\cdot}79b$ beneath the surface. Plastic flow is likely to start at this sub-surface location. Using the Tresca yield criterion (see 'Plasticity' later) it may be shown that the peak pressure for the onset of yielding is about $1{\cdot}7\sigma_y$ where σ_y is the uniaxial flow stress; the average contact pressure is $(2/3)1{\cdot}7\sigma_y \approx 1{\cdot}13\sigma_y$. This reflects the constraint of the surrounding elastic strain field. In the presence of traction across the interface as well as normal contact as in driven gearing, the location of the maximum shear stress moves nearer to the surface. For coefficients of friction $\leq 0{\cdot}1$, τ_{max} occurs on the surface.

STRESS CONCENTRATIONS.—At discontinuities in section, irregularities in uniform stress distribution occur, and local stresses can be far above average values obtaining remote from changes in cross-section. Thus, for a large plate containing an elliptical through-hole of semi-axes a and b, the stress at the ends of the ellipse is

$$s = s_0(1 + 2a/b)$$

where s_0 is the remotely applied uniform stress (Fig. 52). The 'stress concentration factor' K_t for the points at the ends of the a-axis is

$$K_t = s/s_0 = (1 + 2a/b) \qquad (91)$$

For a circular hole $a = b$, and the local stress is 3 times the average stress. The stresses drop off rapidly with distance from the discontinuity.

Tables and charts for K_t in various geometries are available in various references given at the end of this Chapter. Geometries include members with grooves, notches, fillets etc in axial loading, bending, torsion and combined loading. Some have been derived theoretically; some experimentally.

The magnitude of K_t depends on the 'abruptness' or 'sharpness' of the discontinuity. When $a \gg b$ in equation (91), as in crack-like defect, K_t can be very high indeed. In ductile materials, the effect is alleviated (sometimes) by yielding of the tip of the crack (since $s > s_y$) without further damage. In other cases cracks may propagate and lead to failure, as discussed under 'Fracture Mechanics'. There we are concerned with the whole *field* of stress and strain around discontinuities (not merely at one point) to determine the critical loads for fracture.

When stresses fluctuate, K_f is the 'fatigue stress concentration factor' or 'fatigue strength reduction factor'. It is the ratio of the fatigue limit of a specimen containing the notch feature of interest to the fatigue limit of an equivalent plain specimen. Experiments show that $K_f < K_t$, the difference increasing as K_t increases. Modern thinking connects K_f to the relative extent of plastic zones at (*i*) the tip of a sharp fatigue crack and (*ii*) the notch itself out of which the fatigue crack advances, see Smith and Miller (1977).

FRACTURE MECHANICS.—The subject of fracture mechanics is, for practical design purposes, what we might call 'strength of materials for cracked bodies'. Historically, the effects of stress concentration have been incorporated in design procedures but it has been found that new parameters, involving both stress *and* size of crack (rather than stress alone), are necessary for a proper description of the mechanics of cracking. We are interested in predicting either the safe working stress in the presence of a known flaw, or the critical size of flaw associated with a given working stress.

There are two approaches to the determination of elastic fracture stresses, the one based upon consideration of the complicated stress fields around the tips of cracks, the other based upon energy methods (see earlier). Both have their parallels in the Theory of Elasticity on the one hand, and Castigliano's theorems on the other. The results are the same both routes, of course, but new mechanical property parameters must be introduced.

The energy approach involves the specific work of fracture R with units J/m^2—also called G_c which is the work required to propagate the crack by unit area, and fracture stress formulae take the form

$$\sigma_{crack} \propto \sqrt{ER/na} \text{ or } \sqrt{EG_c/na} \qquad (92)$$

where E is Young's modulus and a the size of the crack ('size' may be length, half-length, depth of the crack

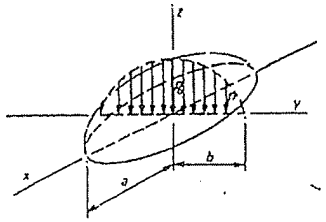

FIG. 50.

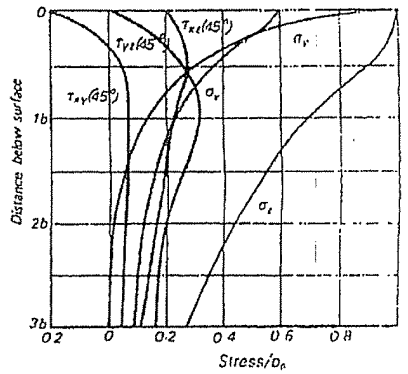

FIG. 51.

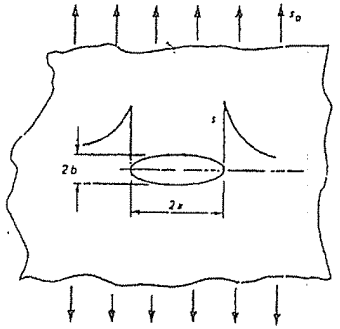

FIG. 52.

depending on circumstances). The form of equation (92) was first presented by Griffith in 1920. We see that σ_{crack} is high when the crack size is small and vice-versa. There is a critical crack length below which the crack will not run for a given applied stress. For example, in beer bottle glass for which $E = 70$ GPa and $R = 20$ J/m^2 has a strength of some 170 MPa. The Griffith flaw size is therefore some 30 μm, and bulk glass is contaminated by such minute starter cracks. Glass fibres, on the other hand, have fewer such flaws which explains their improved strength.

Formulae for fracture stresses obtained by the Theory of Elasticity route are written

$$K_c = \sigma_{crack}\sqrt{na}.Y \qquad (93)$$

where K_c is the so-called critical *stress intensity factor* (*not* to be confused with *stress concentration factor*) and the non-dimensional coefficient Y is the 'shape-factor' which accounts for different shape bodies, crack orientations, and methods of loading. We observe that K_c has peculiar units, written N/m$^{3/2}$ or Pa$\sqrt{m}$, and this makes it difficult to get a physical feel for the parameter. Comparison of equations (92) and (93) show that $(1/Y)$ is the constant of proportionality in equation (92) and, more particularly, that

$$K_c^2 = ER = EG_c$$

The reason for the peculiar units is now obvious: K_c is a combination of two more easily understood

ENGINEERING

Strength of Materials

Part II Advanced

Third Edition

S Timoshenko

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PREFACE TO THE THIRD EDITION

In preparing the latest edition of this book, a considerable amount of new material has been added. Throughout the text, the latest references have been inserted, as well as new problems for solution and additional figures. The major changes in text material occur in the chapters on torsion, plastic deformation and mechanical properties of materials.

With regard to torsion, the problem of the twist of tubular members with intermediate cells is considered, as well as the torsional buckling of thin-walled members of open cross section. Each of these topics is important in the design of thin-walled structures such as the structural components of airplanes. In the chapter on plastic deformation the fundamental principles of limit design are discussed. Several examples of the application of the method to structural analysis are presented.

Major additions were made to the chapter on mechanical properties of materials, so that this single chapter now contains over 160 pages. The purpose of this expanded chapter is to focus attention on the recent developments in the field of experimental studies of the properties of structural materials. Some of the topics discussed are (1) the influence of imperfections on the ultimate strength of brittle materials and the "size effect"; (2) comparison of test results for single-crystal and polycrystal specimens; (3) the testing of materials under two- and three-dimensional stress conditions and various strength theories; (4) the strength of materials under impact; (5) fatigue of metals under various stress conditions and methods for improving the fatigue resistance of machine parts; and (6) strength of materials at high temperature, creep phenomenon and the use of creep test data in design. For the reader who desires to expand his knowledge of these topics further, the numerous references to the recent literature will be helpful. Finally, in the concluding article of the book, information for the proper

CHAPTER VIII

STRESS CONCENTRATION

55. Stress Concentration in Tension or Compression Members.—In discussing simple tension and compression it was assumed that the bar was of prismatic form. Then for centrally applied forces the stress is uniformly distributed over the cross section. A uniform stress distribution was also assumed in the case of a bar of variable cross section (see Fig. 14, Part I, p. 16), but this is an approximation which gives satisfactory results only when the variation in the cross section is gradual. Abrupt changes in cross section give rise to great irregularities in stress distribution. These irregularities are of particular importance in the design of machine parts subjected to variable external forces and to reversal of stresses. Irregularity of stress distribution at such places means that at certain points the stress is far above the average value, and under the action of reversal of stresses progressive cracks are likely to start. The majority of fractures of machine parts in service can be attributed to such progressive cracks.

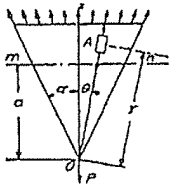

Fig. 173.

To illustrate the stress distribution in a bar of variable cross section under tension, let us consider a symmetrical wedge of constant thickness h loaded as shown in Fig. 173. An exact solution shows (see p. 60) that there is a simple radial stress distribution. An element in the radial direction at any point A is in a condition of simple radial tension. The magnitude of this radial tensile stress is given by the equation

$$\sigma_r = k\frac{P\cos\theta}{hr}, \qquad (a)$$

in which θ is the angle between the x axis and the radius OA, r is the

distance of the point A from O, and $k = 1/(\alpha + \frac{1}{2}\sin 2\alpha)$ is a factor depending on the angle 2α of the wedge.

The distribution of the normal stresses σ_x over any cross section mn perpendicular to the axis of symmetry of the wedge is not uniform. Using eq. (17), Part I, p. 38, and substituting $r = a/\cos\theta$ in eq. (a) above, we find

$$\sigma_x = \sigma_r\cos^2\theta = \frac{kP\cos^4\theta}{ah}. \qquad (b)$$

This shows that the normal stress is a maximum at the center of the cross section ($\theta = 0$) and a minimum at $\theta = \alpha$. The difference between the maximum and minimum stresses increases with the angle α. When $\alpha = 10°$, this difference is about 6 per cent of the average stress obtained by dividing the load P by the area of the cross section mn. Analogous conclusions also may be drawn for a conical bar. It may be shown that the distribution of normal stresses over a cross section approaches uniformity as the angle of the cone diminishes.

This discussion shows that the assumption of uniform distribution of normal stresses over a cross section of a nonprismatic bar gives satisfactory results if the variation in cross section along the bar is gradual. However, the conditions are quite different when there are abrupt changes in the cross section. At such points the distribution of the stresses is very far from uniform and results obtained on the assumption of uniform stress distribution are entirely misleading. Several examples of abrupt change in cross section are discussed in the subsequent articles.

56. Stresses in a Plate with a Circular Hole.—If a small circular hole [1] is made in a plate subjected to a uniform tensile stress σ, a high stress concentration takes place at the points mn (Fig. 174a). The exact theory [2] shows that the tensile stress at these points is equal to 3σ. The theory also shows that this stress concentration is of very localized character and is confined to the immediate vicinity of the hole.

[1] The diameter of the hole is less, say, than one-fifth of the width of the plate.

[2] This theory was given by Kirsch, *Z. Ver. deut. Ing.*, 1898. See also Timoshenko and Goodier, *Theory of Elasticity*, p. 78, 1951.

chromium in an amount sufficient to increase the ordinary corrosion resistance of the steel also raises the corrosion fatigue limit considerably above the limit for carbon or nickel steels.[149]

Endurance tests in an atmosphere of dry steam [150] showed no effect on the endurance limit, but in the case of steam containing air or water a lowering of the endurance limit was observed. Experiments in a vacuum [151] showed that the endurance limit of steel is about the same as in air, while experiments with copper and brass in a vacuum demonstrated an increase in the endurance limit of at least 14 and 16 per cent, respectively.

There are many known cases of failures in service which may be attributed to corrosion fatigue. These include failures of such parts as marine propeller shafts, water-cooled piston rods of marine oil engines, turbine blades, locomotive springs, pump rods in oil wells, boilers and superheater tubes, etc. In many cases corrosion fatigue failures were eliminated by introducing corrosion-resistant materials. McAdam's experiments with corrosion-resistant steels showed that such steels give very satisfactory results in corrosion fatigue tests. Later experiments with special bronzes [152] showed that phosphor bronze and aluminum bronze, tested under extremely corrosive conditions, have a remarkable corrosion fatigue resistance, comparing favorably with the best stainless steels.

Protective coatings [153] and surface cold-working [154] of parts subjected to corrosive fatigue have also been successfully used in eliminating failures.

Effect of Residual Stresses.—Residual stresses are usually produced during heat treatment of machine parts and during welding of structures, and the question arises as to the effect of these stresses on the endurance limit. Experiments with quenched steel specimens tested in a rotating-beam fatigue-

[149] See McAdam, *Trans. A.S.M.E., Appl. Mech. Div.*, 1928.
[150] See T. S. Fuller, *Trans. Am. Soc. Steel Treat.*, Vol. 19, p. 97, 1931.
[151] H. J. Gough and D. G. Sopwith, *J. Inst. Metals*, Vol. 49, p. 93, 1932.
[152] H. J. Gough and D. G. Sopwith, *J. Inst. Metals*, Vol. 60, p. 143, 1937.
[153] D. G. Sopwith and H. J. Gough, *J. Iron and Steel Inst.*, 1937.
[154] O. Föppl, O. Behrens and T. Dusold, *Z. Metallkunde*, Vol. 25, 1933.

testing machine showed [155] that the residual stresses are reduced to less than one-quarter of their initial value by the application of cycles of reversed stress. The effect of the residual stresses on the endurance limit was negligible. Similar conclusions were also obtained from fatigue tests of welded I beams.[156] E. E. Weibel showed the unfavorable effect of residual stresses produced in coil springs.[157]

Effect of Surface Finish.—The effect of surface finish on the endurance limit has also been studied. Tests were made on 0.49 per cent carbon steel with an ultimate strength of 95,000 lb per sq in. and an ordinary endurance limit of 48,000 lb per sq in. By taking 100 as the endurance limit for highly polished specimens, the following results were obtained for various finishes: [158] ground finish 89, smooth-turned finish 84, rough-turned finish 81. Tests with 0.02 per cent carbon steel (Armco iron) gave for the last two types of finish 92 and 88, respectively. Similar experiments were made with 0.33 per cent carbon steel by W. N. Thomas,[159] who measured the magnitude of the scratches in various finishes with a microscope. Other experiments were made by W. Zander.[160]

Table 26 at the end of this chapter gives the results obtained in static and endurance tests of certain steels used in engineering.

87. Fatigue and Stress Concentrations.—In discussing the stress concentrations produced by sharp variations in the cross sections of bars and shafts (see Chap. 8) it was indicated that such stress concentrations are especially damaging in the

[155] See H. Büller and H. Buchholtz, *Stahl u. Eisen*, Vol. 53, p. 1330, 1933, and *Mitt. Forsch.-Inst., Verein. Stahlwerke (Dortmund)*, Vol. 3, p. 235, 1933.
[156] E. H. Schulz and H. Buchholtz, *Stahl u. Eisen*, Vol. 53, p. 545, 1935.
[157] *Trans. A.S.M.E.*, Vol. 57, p. 501, 1935. See also F. Wever and G. Martin, *Mitt. Kaiser-Wilh. Inst. Eisenforsch. (Düsseldorf)*, Vol. 21, p. 218, 1939, and C. W. MacGregor, in W. R. Osgood, ed., *Residual Stresses in Metals and Metal Construction*, New York, 1954.
[158] See H. F. Moore and J. B. Kommers, *Univ. of Illinois Eng. Exp. Sta. Bull.*, No. 124, p. 683, 1921.
[159] *Engineering*, Vol. 116, p. 483, 1923. Later developments in investigating surface roughness are discussed in the paper by S. Way, *loc. cit.*, p. 505.
[160] Dissertation, Technische Hochschule, Braunschweig, 1928.

case of varying stresses. In machines, stress concentrations are always present owing to fillets, grooves, holes, keyways, etc., and experience shows that most fatigue cracks begin at points of stress concentration. Several examples of such failures will now be briefly discussed.

Figure 321 represents[161] fatigue failures of circular shafts with transverse holes and subjected to the action of reversed

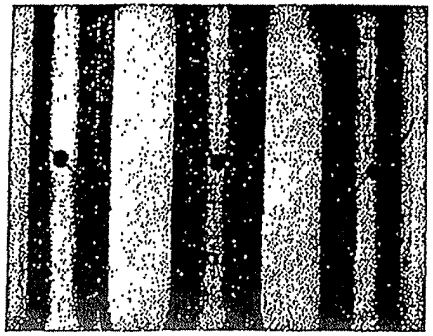

FIG. 321.

torsion. The maximum stress in this case occurs at the edge of the hole along a plane inclined 45° to the axis of the shaft (see p. 305). At these points the cracks begin and gradually develop along a helical path following the direction of one of the principal stresses.

Figure 322 shows the torsional fatigue failure of a shaft of a large motor-generator set which unfortunately operated near resonance.[162] The crack started at the keyway, where a high stress concentration took place, and gradually developed along the helical path. The helical crack corresponding to the direc-

[161] See the paper by A. Thum, *Forschung*, Vol. 9, p. 57, 1938.

[162] Figs. 322–325 are taken from a paper by R. E. Peterson presented at a conference on Strength of Materials Problems in Industry, at the Massachusetts Institute of Technology, July 1937. The mechanism of crack growth is also discussed by Peterson, *J. Appl. Mech.*, Vol. 1, p. 157, 1933. Many examples of fatigue failures of prime movers are described in the paper by L. W. Schuster, *Proc. Inst. Mech. Engrs. (London)*, April 1933.

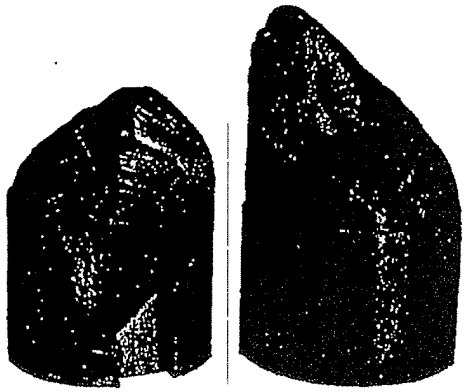

FIG. 322.

the second principal stress can also be seen on the phot

Figure 323 represents a torsion failure of a shaft of driven generator. A high stress concentration at t

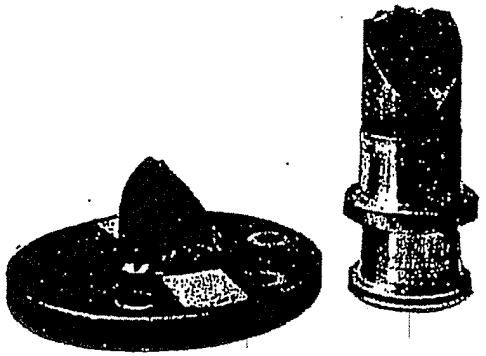

FIG. 323.

all fillet resulted in several helical cracks, which when ned together produced the saw-toothed appearance. In t. 324 are shown fatigue cracks which developed gradually

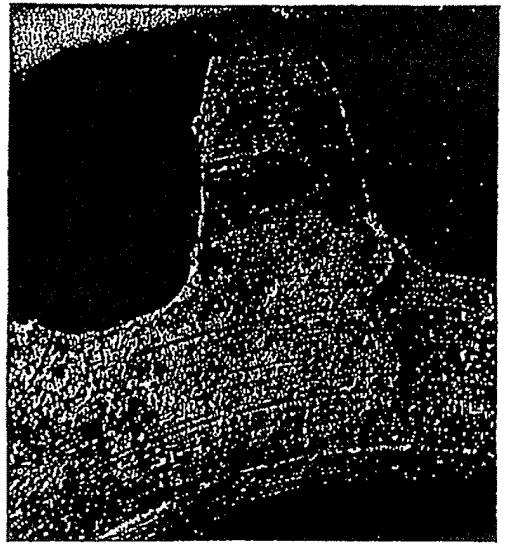

FIG. 324.

at the roots of gear teeth. The points of high stress concentration were produced by the bending of the teeth as cantilevers.

Finally, Fig. 325 represents a characteristic fatigue failure of a heavy helical spring. The crack started from the inside,

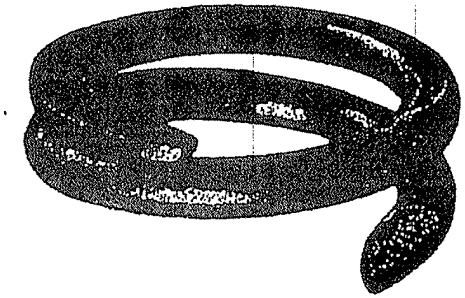

FIG. 325.

as theory predicts (see Part I, p. 291), and again followed the direction of one of the principal stresses. All these pictures clearly demonstrate the damaging action produced by stress concentration, and it is clear that this factor must be seriously considered in the design of machine parts.[163]

The early fatigue tests made with specimens having sharp changes of cross section showed that there was a reduction in strength due to the stress concentration, but this reduction was usually smaller than expected from the magnitude of the calculated stress concentration factor. For instance, in the case of flat steel specimens with small circular holes subjected to direct stress, the theoretical factor of stress concentration is 3 (see p. 301). If the magnitude of the peak stress is the controlling factor in endurance tests, it would be expected that the tension-compression load required to produce fatigue failure of a specimen with a hole would be about one-third of the load for a specimen without a hole. However, experiments showed that in this case the reduction in strength due to the stress concentration is small as compared with the calculated effect.[164]

To explain this discrepancy and to give the necessary information for designers, a very extensive series of tests were made by R. E. Peterson at the Westinghouse Research Laboratories.[165] Geometrically similar cantilever test specimens varying in diameter from 0.1 in. to 3 in., with a fillet or with a transverse circular hole and of different materials, as given in Table 23, were tested in special fatigue-testing machines.[166] The results of these tests for specimens with fillets are given

[163] It is very important in practice to have some means for detecting cracks as soon as they appear. Various methods of crack detection are described by Charles Lipson in his article in M. Hetényi, ed., *Handbook of Experimental Stress Analysis*, 1950.

[164] B. P. Haigh and J. S. Wilson, *Engineering*, Vol. 115, p. 446, 1923.

[165] R. E. Peterson, *J. Appl. Mech.*, Vol. 1, pp. 79 and 157, 1933; and R. E. Peterson and A. M. Wahl, *ibid.*, Vol. 3, p. 15, 1936. See also the progress reports of the Research Committee on Fatigue of Metals, *Proc. Am. Soc. Test. Mat.*, Vol. 42, p. 145, 1942, and Vol. 43, 1943.

[166] A description of these machines is given in the paper by R. E. Peterson, *Proc. Am. Soc. Test. Mat.*, Vol. 29, p. 371, 1929.

TABLE 23: MATERIALS USED IN FATIGUE TESTS BY PETERSON

Steel	Chemical Composition, %								Y.P. lb/in.²	Ult. lb/in.²	Elong., %
	C	Mn	Si	S	P	Ni	Cr	Mo			
Medium carbon *	0.45	0.79	0.18	0.03	0.013	—	—	—	32,500	76,000	32
Ni-Mo †	0.52	0.68	0.19	—	0.014	2.96	—	0.38	45,500	91,000	26
Ni-Cr ‡	0.54	0.65	—	—	—	1.38	0.61	—	91,000	120,000	24

* Normalized: 1560° F, air-cooled.
† Normalized and drawn: 1750° F, air-cooled; 1460° F, air-cooled; 1160° F, furnace-cooled.
‡ Quenched and drawn: 1475° F, oil-quenched; 1200° F, furnace-cooled.

in Fig. 326. The smaller diameters of the specimens are taken as abscissas while the ordinates represent the ratios k_f of the endurance test loads for plain specimens to the endurance

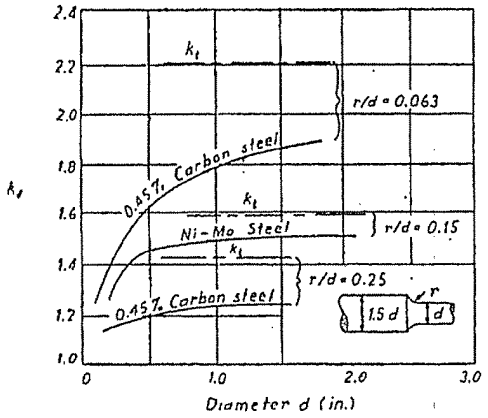

FIG. 326.

test loads for the corresponding specimens with stress concentrations. Similar results were obtained for specimens with transverse holes.

The horizontal lines in Fig. 326 give the values of the stress concentration factors obtained for each fillet size by a direct measurement of strain at the points of maximum stress

concentration (see p. 329). These values are designated by k_t and are called *theoretical values* of stress concentration in the following discussion. If the fatigue strength of the specimen depends only on the peak stress, then k_t must evidently be equal to k_f.

On a basis of his tests, Peterson came to the following conclusions:

(1) In some cases fatigue results are quite close to theoretical stress concentration values. This conclusion is of great practical importance, since a general idea seems to exist, based on some early experiments, that fatigue data for stress concentration cases are always well below theoretical values, i.e., on the safe side for design purposes.

(2) Fatigue results for alloy steels and quenched carbon steels are usually closer to the theoretical values than are the corresponding fatigue results for carbon steels not quenched. It was expected in these tests that the theoretical values of k_t would be reached for all steels provided the specimens were made large enough, but Fig. 326 shows that the curves for normalized 0.45 per cent carbon steel are apparently asymptotic to values considerably below the theoretical.

(3) With a decrease in the size of the specimen the reduction in fatigue strength due to a fillet or hole becomes somewhat less; and for very small fillets or holes the reduction in fatigue strength is comparatively small. This can be clearly seen from the curves in Fig. 326.

Another way of presenting fatigue test results in order to show the extent to which the theoretical values k_t are reached, is obtained by introducing the quantity

$$q = \frac{k_f - 1}{k_t - 1}, \qquad (a)$$

which is called the *sensitivity factor*. As k_f approaches the value k_t, the value of q approaches unity, and when the stress concentration has only a small effect on fatigue strength, k_f is close to unity and q approaches zero. The values of q for several forms of stress raiser and for two kinds of steel are

presented [167] in Fig. 327, in which the fillet or hole radius is taken as abscissa. It is seen that the sensitivity index is not a constant. It depends not only on the kind of material but also on the size of the specimens. In the case of alloy steels

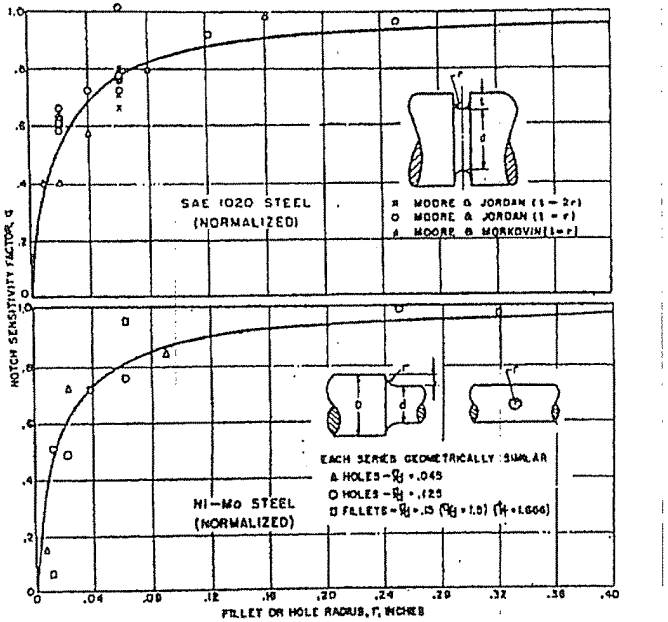

FIG. 327.

and for larger specimens, q approached unity; while for a coarser material, 0.45 per cent carbon steel, q approximates a somewhat lower value.[168]

On the basis of the above discussion the use of the theoretical value k_t of stress concentration can be recommended

[167] See R. E. Peterson's book, *loc. cit.*, p. 479.

[168] Tests of cast iron show that stress concentrations have little effect on fatigue test results; see A. Thum and H. Ude, *Z. Ver. deut. Ing.*, Vol. 74, p. 257, 1930.

in the design of large-size machine parts, and also in the case of the finer-grained steels, such as alloy steels and heat-treated carbon steels. For parts of small dimensions and for coarse materials the reduced value of the stress concentration factor can be used. This value, from eq. (*a*), is

$$k_f = q(k_t - 1) + 1. \qquad (b)$$

The values of q obtained experimentally for fillets, holes and grooves, and represented in Fig. 328, can be used as a guide

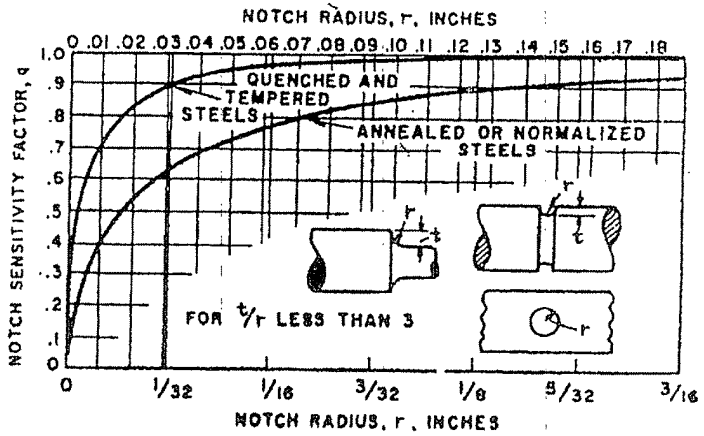

FIG. 328.

in selecting the proper values of k_f for other cases of stress concentration.[169]

Fatigue fractures resemble static fractures of brittle materials in that they occur practically without plastic deformation. The crack starts at some local imperfection and progresses in the direction normal to the tensile stress. It is

[169] See R. E. Peterson's book, *loc. cit.*, p. 479, and C. E. Phillips and R. B. Heywood, *Proc. Inst. Mech. Engrs. (London) Appl. Mech.*, Vol. 165, p. 113, 1951. Torsional fatigue tests on 2¾-in.-diameter shafts made by T. W. Bunyon and H. H. Attla, *Trans. Engrs. Shipbuilders Scot.*, 1953, showed for the sensitivity factor a smaller value ($q = \frac{D}{H}$) than the values obtained in bending tests by R. E. Peterson.

therefore reasonable to expect that the probability theory developed in studying fracture of brittle materials (see p. 399) can also be used in fatigue tests.[170] Pursuant to this idea we must expect that the endurance limit of a material will decrease with an increase in size of the test specimen. Working with fatigue tests in bending, several experimenters noticed a diminution of fatigue strength with an increase in diameter of the specimens.[171] Much larger *size effect* was found in testing specimens with various kinds of stress concentrations, but it seems that no attempt has yet been made to study this phenomenon by applying probability theory.[172] The problem becomes very complicated because the volume of highly stressed material in such cases is usually very small, and it becomes necessary to consider the grain size of crystalline materials. While we speak of geometrically similar specimens of the same material, it is obvious that their metallographic structure is not geometrically similar, and this fact may affect the fatigue tests. Considering a region of peak stress, a different result may be expected when only a few grains are contained in that region from the result if many thousands of grains are contained in the same region. The relationship between the sensitivity factor q obtained from fatigue tests and the grain size of the materials is discussed in a paper by R. E. Peterson.[173]

88. Reduction of the Effect of Stress Concentrations in Fatigue.—It can be appreciated that the problem of reducing the damaging effect of stress concentrations is of primary importance to designers. Some lowering of stress concentrations can be obtained by a suitable change in design. For example, a design can be improved considerably by eliminating sharp

[170] See the paper by W. Weibull, *Trans. Roy. Inst. Technol. (Stockholm)*, No. 27, 1949.

[171] R. E. Peterson, *Proc. Am. Soc. Test. Mat.*, Vol. 29$_2$, p. 371, 1929; R. Faulhaber, *Mitt. Forsch.-Inst., Verein. Stahlwerke (Dortmund)*, Vol. 3, p. 153, 1933; and O. J. Horger and H. R. Neifert, *Proc. Am. Soc. Test. Mat.*, Vol. 39, p. 723, 1939.

[172] This problem was discussed by R. E. Peterson, *Proc. Am. Soc. Metals*, 1948.

[173] See *Contributions to the Mechanics of Solids, Dedicated to Stephen Timoshenko by His Friends*, New York, p. 179, 1938.

reentrant corners and introducing fillets of generous radius, by designing fillets of proper shape, by introducing relieving grooves, etc. In Fig. 329 are shown methods for reducing the

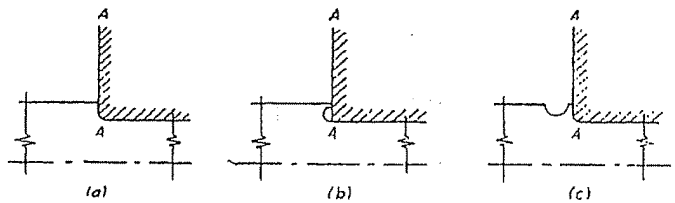

FIG. 329.

stress concentration at a shoulder of a shaft, while maintaining the positioning line AA. The stress can be reduced by cutting into the shoulder and introducing a fillet of larger radius without developing interference with the fitted member, as shown in Fig. 329*b*. If the shoulder height is too small, a relief groove may be used as shown in Fig. 329*c*.

In Fig. 330 two different bolt-and-nut designs are shown. In Fig. 330*a* the nut is in compression while the bolt is in

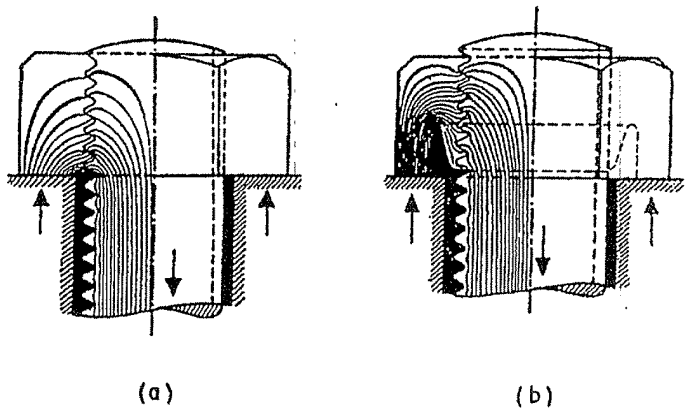

FIG. 330.

tension. High stress concentration takes place at the bottom of the thread in the face of the nut, and under the action of variable forces, fatigue fracture occurs in that plane.[174] In the lip design, Fig. 330*b*, the peak stress is somewhat relieved because the lip is stressed in the same direction as the bolt. Fatigue tests show [176] the lip design to be about 30 per cent stronger.

Sometimes these relieving measures are not sufficient to eliminate fatigue failures. As an important example let us consider the typical failures which occur at the wheel seats of locomotive and railroad-car axles, at the wheel or bearing seats of automobile axles, at the pressed or fitted bits of long drill rods in oil-well operations, etc. All these cases of fitted members subjected to the action of variable stresses have been a constant source of fatigue failures. Considering, for example, the case of a wheel hub pressed on an axle, Fig. 331*a*,

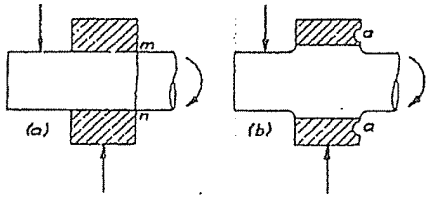

Fig. 331.

we can see that a high stress concentration combined with friction [176] is produced at the reentrant corners *m* and *n*. During rolling of the axle a reversal of stress at points *m* and *n* takes place, and finally a fatigue failure over the cross section *mn*, as shown in Fig. 332, may occur. Stress concentrations

[174] J. N. Goodier, *J. Appl. Mech.*, Vol. 62, p. 11, 1940. See also M. Hetényi, *Proc. Soc. Exp. Stress Anal.*, Vol. 1, p. 147, 1943.

[175] H. Wiegand, thesis, Tech. Hochschule, Darmstadt, 1933. See also S. M. Arnold, *Mech. Engrg.*, Vol. 65, p. 497, 1943.

[176] Regarding fretting corrosion and fatigue, see G. A. Tomlinson, P. L. Thorpe and H. J. Gough, *Proc. Inst. Mech. Engrs. (London)*, Vol. 141, p. 223, 1939. See also O. J. Horger, *Symposium on Fretting Corrosion*, American Society for Testing Materials, 1953.

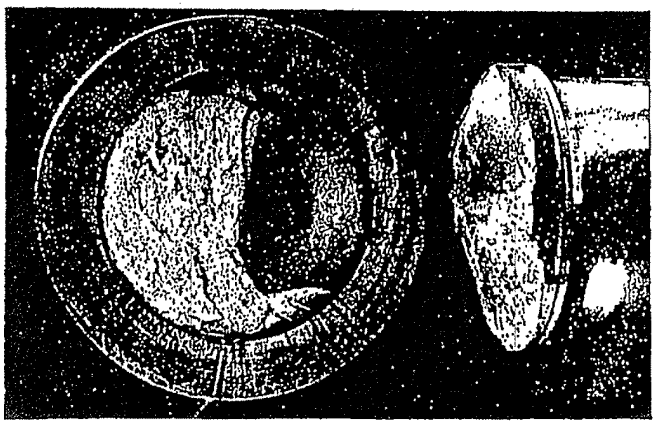

Fig. 332.

can be somewhat reduced by introducing raised seats and fillets as shown in Fig. 331*b*. A further improvement is obtained by introducing the relief groove *a*, Fig. 331*b*. Although such changes are an improvement, they are not sufficient in this case. Experience shows that the mere press fit of a hub on an axle, Fig. 331*a*, reduces the fatigue strength of the axle to less than half of its initial strength, while the changes shown in Fig. 331*b* raise the fatigue strength of the axle perhaps no more than 20 per cent.

To improve this condition and eliminate fatigue failures, surface cold-rolling of the axle in the region of stress concentration has been successfully applied. The early experiments [177] with surface cold work were made on small specimens, and in order to obtain sufficient information for practical applications, an extensive series of laboratory tests with large specimens

[177] Improvement of fatigue strength by surface cold-working was introduced by O. Föppl, *Stahl u. Eisen*, Vol. 49, p. 575, 1929. It was applied in various fatigue tests at the Wöhler-Institut. See *Mitt. Wöhler-Inst.*, Vols. 1–37, 1929–40. See also A. Thum and F. Wunderlich, *Mitt. Materialprüfungsanstalt, Tech. Hochschule (Darmstadt)*, Vol. 5, 1934; and R. Kühnel, *Stahl u. Eisen*, Vol. 110, p. 39, 1932.

EXHIBIT 3

US005192307A

United States Patent [19]

Wall

[11] Patent Number: 5,192,307

[45] Date of Patent: Mar. 9, 1993

[54] ANGIOPLASTY STENT

[76] Inventor: W. Henry Wall, 5139 Jimmy Carter Blvd., Ste. 201, Norcross, Ga. 30071

[21] Appl. No.: 831,354

[22] Filed: Feb. 5, 1992

Related U.S. Application Data

[62] Division of Ser. No. 129,834, Dec. 8, 1987.

[51] Int. Cl.[5] A61F 2/04

[52] U.S. Cl. 623/1; 623/12; 604/194; 604/198

[58] Field of Search 606/194, 195, 193, 192, 606/196-200; 623/1, 12; 604/96

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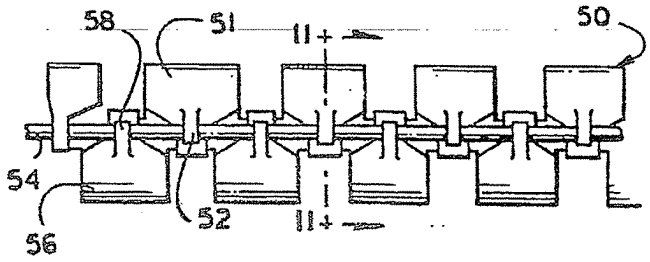
Primary Examiner—David Isabella
Assistant Examiner—Debra S. Brittingham
Attorney, Agent, or Firm—James B. Middleton

[57] ABSTRACT

A prosthesis for use in preventing re-stenosis after angioplasty is formed of plastic or sheet metal, and is expandable and contractible for placement. The prosthesis can be inserted while in a collapsed position, then expanded and locked at the larger diameter. Spring force can be provided by the material itself, or metal springs can be embedded within the walls of the prosthesis. Preferably, the walls have holes therethrough to promote tissue growth; and, in one embodiment, the holes are in the form of slots so that the prosthesis is segmented and can bend longitudinally.

7 Claims, 2 Drawing Sheets



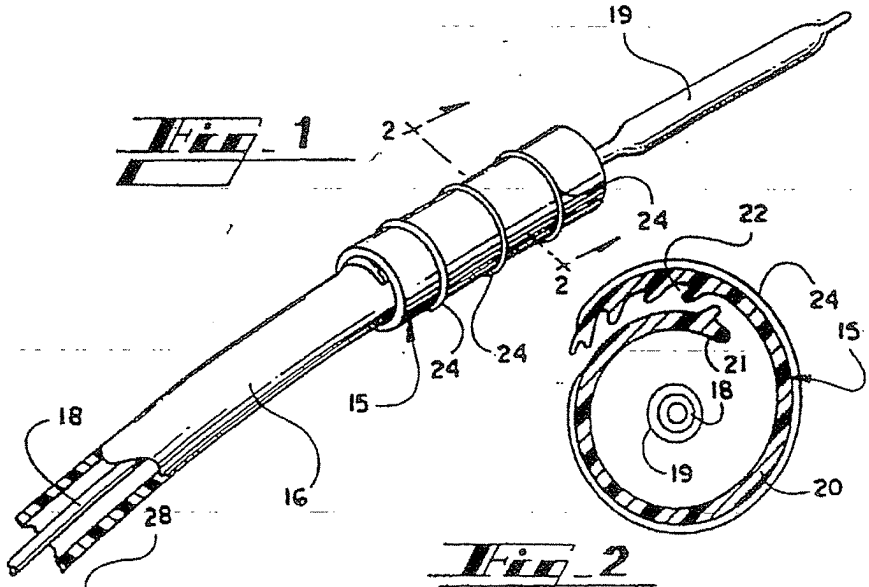
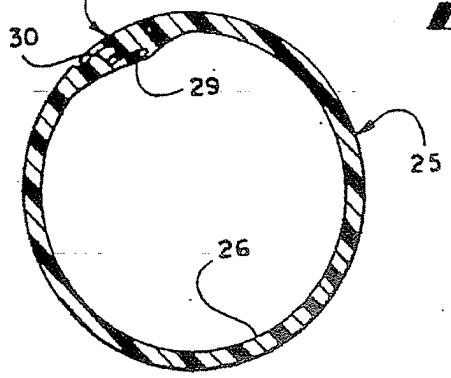


Fig_1

Fig_2



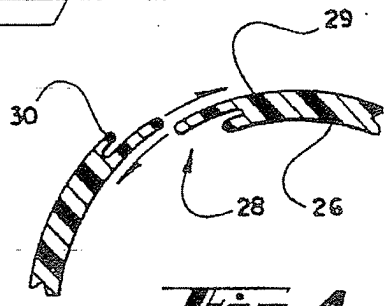


Fig_3

Fig_4

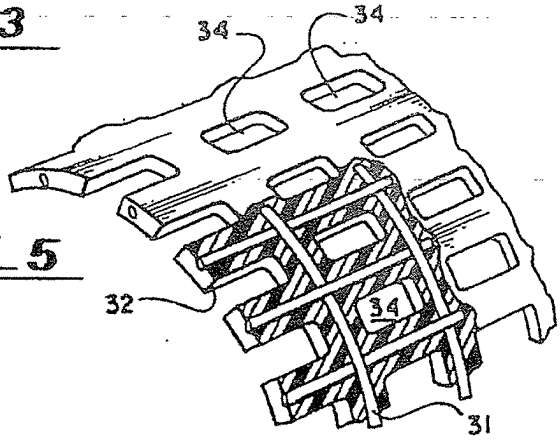


Fig_5

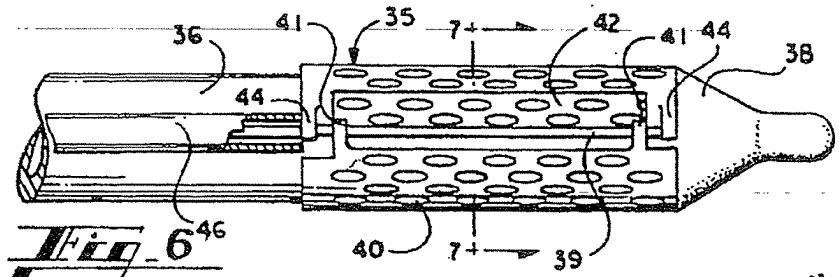


Fig_6

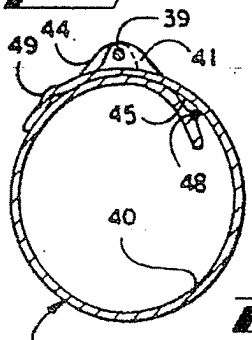


Fig_7

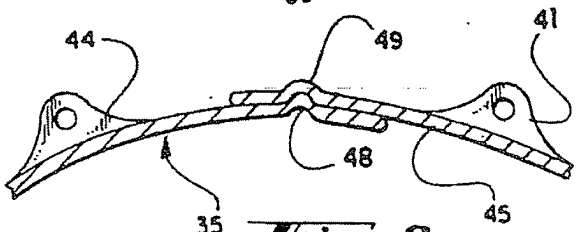


Fig_8

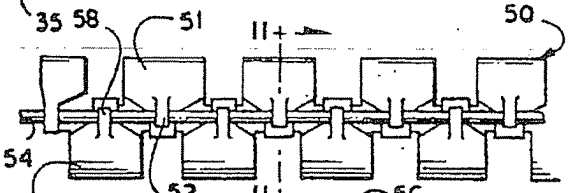


Fig_9

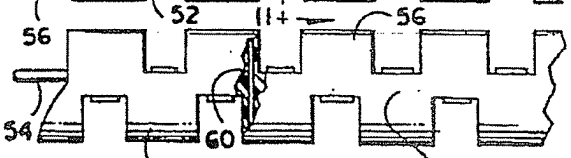


Fig_10

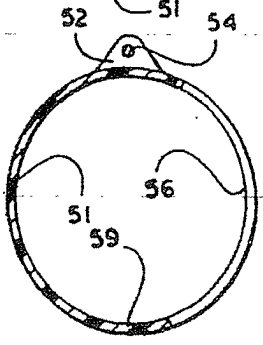


Fig_11

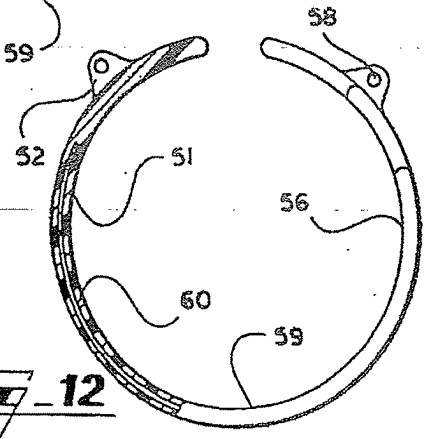


Fig_12

ANGIOPLASTY STENT

CROSS REFERENCE TO RELATED APPLICATION

This application is a division of the pending application by the same inventor, filed Dec. 8, 1987, under Ser. No. 129,834, pending.

INFORMATION DISCLOSURE STATEMENT

There has been considerable use of balloon angioplasty due to stenosis in arteries having atherosclefotic plaque and the like in an effort to enlarge the lumen and to provide adequate blood flow. While such angioplasty has been successful, it has been found that in many cases re-stenosis requires that the procedure be repeated.

More recently, there have been efforts at following the balloon angioplasty with placement of a stent, the stent being in the nature of a sleeve that will mechanically maintain some minimum lumen diameter.

It will be obvious that, in order to place a stent utilizing the balloon angioplasty technology, the stent must necessarily have a sufficiently small external diameter to be moved into the desired area by some means such as a catheter, then to be expanded both to be held in place by the arterial elasticity and to provide the minimum lumen diameter. Prior stents have generally taken the form of wire mesh that is collapsed for placement into the artery, then expanded, either by means of a balloon or by its own elasticity. The stent is generally held in place simply by the arterial elasticity in the first instance, and it has been found that epithelialization takes place throughout the stent so that the entire stent becomes effectively embedded in the vessel wall.

The prior art stents, being woven stainless steel wire or the like tend not to be very flexible longitudinally so that their primary use is in straight portions of vessels. Also, inflation of the balloon is required to expand the wire to its desired size in some cases, while other wire mesh stents tend to take a particular size, and must be held by a sleeve or the like during placement.

SUMMARY OF THE INVENTION

This invention relates generally to prostheses, and is more particularly concerned with a prosthesis in the form of a stent to be placed in a vessel for mechanically maintaining an opening.

This invention provides a stent for maintaining a minimum opening through an artery or the like, the stent being in the form of a sleeve having a gap so the sleeve has a collapsed position to be assumed during placement of the stent, and an expanded position for use in its final location for maintaining the desired opening. In one embodiment of the invention, the stent may be carried by one catheter while a second coaxial catheter in the nature of a conventional balloon catheter is carried therein. This arrangement allows use of the balloon catheter to provide a mechanical opening in the vessel, then to allow the stent to be slipped into place over the balloon. The balloon can then be used to manipulate the stent for any necessary opening of the stent and disengagement of the stent from the coaxial catheter. It is also contemplated that the stent of the present invention can be carried by a single, generally conventional balloon catheter.

The stent of the present invention may selectively be biased towards a closed position and lockable in an open position, or biased in an open position and lockable in a closed position. In the former case, the stent will be put into place in its collapsed condition, then forcibly expanded by a balloon or the like to the desired locked condition. In the latter case, the stent may be held by a pin or the like in its collapsed condition, and the pin removed to allow the stent to assume its open position.

The stent of the present invention may be made from any of numerous materials, including metal or the like, and also including various plastic materials. The plastic materials may be simply homogeneous molded plastics, or may comprise a plastic covering over a knit or woven mesh. The knit or woven mesh may, in turn, be metal or plastic. The precise material can be selected to achieve the desired features of the stent.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will become apparent from consideration of the following specification when taken in conjunction with the accompanying drawings in which:

FIG. 1 is a perspective view showing one form of stent made in accordance with the present invention and carried by a coaxial catheter;

FIG. 2 is an enlarged cross-sectional view taken substantially along the line 2—2 in FIG. 1;

FIG. 3 is a cross-sectional view of a slightly modified form of stent shown in its open and locked position;

FIG. 4 is a fragmentary view showing the stent of FIG. 3 after expansion beyond its maximum, open position;

FIG. 5 is a fragmentary perspective view, partially in cross-section, showing one form of material for use in constructing the stents of the present invention;

FIG. 6 is an elevational view showing another modified form of stent made in accordance with the present invention, the stent being carried on a catheter;

FIG. 7 is a cross-sectional view taken substantially along the line 7—7 in FIG. 6;

FIG. 8 is a fragmentary view showing the stent of FIG. 7 after expansion;

FIG. 9 is a top plan view of another modified form of stent made in accordance with the present invention, the stent being shown without the carrying catheter;

FIG. 10 is a bottom plan of the device show in FIG. 9;

FIG. 11 is an enlarged cross-sectional view taken substantially along the line 11—11 in FIG. 9; and,

FIG. 12 is a view similar to FIG. 11 but showing the stent in its expanded condition.

DETAILED DESCRIPTION OF THE EMBODIMENTS

Referring now more particularly to the drawings, and those embodiments of the invention here presented by way of illustration, FIG. 1 shows a stent generally indicated at 15, the stent 15 being carried by a catheter 16. The catheter 16 is one of two coaxial catheters, the other catheter 18 being a generally conventional balloon catheter having the balloon 19 at its distal end.

It will be understood by those skilled in the art that, in conventional, balloon angioplasty, a catheter such as the catheter 18 is threaded through the arterial system to place the balloon at the location of the stenosis. The balloon 19 is then inflated to urge the arterial wall outwardly and open the lumen in the artery. This same technique will be utilized with the arrangement shown in FIG. 1 of the drawings, the balloon 19 acting to

perform the angioplasty; however, after the vessel is sufficiently open by means of the balloon 19, the coaxial catheter 16 will be manipulated to urge the stent 15 in place over the balloon 19. After the stent 15 is over the balloon 19, the balloon 19 will be inflated to urge the stent outwardly to its opened condition.

Referring to FIG. 2 of the drawings, it will be seen that the stent 15 includes a wall 20, the wall 20 having sufficient memory that the stent as a whole tends to maintain its collapsed condition. One end of the wall 20 is provided with a hook 21 for engagement with one of a plurality of complementary hook means 22. The hook 21 will necessarily be biased outwardly sufficiently that, as the hook 21 is urged past the plurality of hook means 22, the hook 21 will engage each of the hooks 22. Because of this arrangement, when the balloon 19 is not further inflated, the hook 21 will remain engaged with one of the hooks 22 to prevent collapse of the stent 15.

It will also be noticed that the stent 15 contains a plurality of generally circumferential ribs 24. It is contemplated that the ribs 24 will engage the arterial walls sufficiently to prevent inadvertent movement of the stent after placement and removal of the catheter 16. As will be discussed hereinafter, the stent 15 may also contain a plurality of openings to allow tissue to grow therethrough and further hold the stent 15 in place.

Looking now at FIGS. 3 and 4 of the drawings, it will be seen that the stent 25 is a slightly modified form of the stent 15. The stent 25 includes the wall 26 which will be biased towards collapse as is the wall 20 of the stent 15. Once the stent 25 is urged to its expanded condition, the interlocking hook means 28 will become engaged as shown in FIG. 3 to prevent collapse of the stent 25 and maintain the stent in its maximum, open condition.

It will be understood that there may be times when the stent is improperly placed, or for other reasons must be removed. With the stent 25, the ends 29 and 30 of the wall 26 are so biased that, when the stent 25 is expanded so far that the ends 29 and 30 are released from engagement, the end 29 will move inwardly and the end 30 will move outwardly. On subsequent release of the stent 25, the walls 29 and 30 have exchanged places so that the hook means 28 cannot now engage. As a result, the stent 25 will collapse to its minimum external diameter.

Though many different materials may be utilized in forming the stents of the present invention, one form of material is illustrated in FIG. 5 of the drawings. In FIG. 5 there is a woven network indicated at 31. This woven network may be metal such as stainless steel or the like, or may be a knit or woven plastic material such as polyester filaments. If the network 31 is made of metal, the intersections can be sonically welded or otherwise heat sealed to one another.

Following provision of the network 31, the network 31 is covered by a plastic material indicated at 32. The material 32 can again be any of numerous materials, so long as the material is implantable. Nevertheless, numerous plastic materials including polyethylene, polyester, polytetraflouroethylene and others can be utilized.

As illustrated in FIG. 5, the network 32 is simply coated with the material 32 so that openings 34 are distributed throughout the material. While the openings 34 are not necessarily so uniformly distributed, it will be understood that the use of a plurality of openings 34 promotes epithelialization to promote incorporation of the stent into the vessel wall.

Turning now to FIG. 6 of the drawings, there is a stent indicated at 35 carried at the end of a catheter 36. The catheter 36 includes a balloon 38 as is known in the art.

While the above described stents have been biased inwardly and have been forced outwardly, the stent 35 is biased outwardly and is forced inwardly and retained by means of a pin 39. For a full understanding of the stent 35, attention is directed to FIG. 6, 7 and 8 of the drawings which show both plan view and cross-sectional views of the stent 35.

The stent 35 is here shown as having a generally smooth wall 40 having a plurality of openings 43 in accordance with the foregoing discussion. The wall 40 is biased outwardly towards its maximum diameter; however, for placement by means of the catheter 36, the stent 35 is urged inwardly to its minimum diameter, and the stent is provided with a first pair of lugs 41 carried on the end 42 of the wall 40, and second pair of lugs 44 carried generally toward the opposite end 45 of the wall 40. When the wall 40 is urged inwardly to collapse the stent 35, appropriate openings in the lugs 41 and 44 are aligned, and the pin 39 is placed therethrough to hold the stent 35 in its collapsed position.

As is shown in FIG. 6 of the drawings, it is contemplated that the pin 39 will be in the form of a wire that extends along the catheter 36, contained within a channel 46. With this arrangement, the pin 39 will extend to the lug 44 at the distal end of the stent 35, and it will be understood that the distal end lug 44 may have a hole that does not extend completely through the lug in order to cover the end of the pin 39. The pin 39 then extends the full length of the stent 35 and into the channel 46. While not here illustrated, it will be understood that the pin 39 extends completely along the length of the catheter 36 so the pin 39 can be manipulated externally of the body so that, at the appropriate moment, the pin 39 can be removed from the lugs 41 and 44 and allow the stent 35 to expand.

As here shown, when the stent 35 expands, the ends 42 and 45 will remain overlapped to some extent. If desired, interlocking grooves 48 and 49 can be provided so the stent 35 has a relatively fixed expanded diameter.

Attention is next directed to FIGS. 9–12 of the drawings which show another modified form of stent. The stent 50 is similar to the stent 35 in that it is biased outwardly and is forcibly held inward by a pin; however, the stent 50 is considerably different from the stent 35 in that the stent 50 is of a somewhat segmented construction to allow longitudinal flexibility.

In the top plan view shown in FIG. 9 of the drawings, it will be seen that the stent 50 includes a plurality of segments 51, each segment 51 having a lug 52 thereon for receipt of a pin 54. The segments 51 are interspersed with segments 56 on the opposite side of the pin 54, the segments 56 having lugs 58 thereon. As is better shown in FIG. 10 of the drawings, there is a generally continuous spine 59 extending along the bottom of the stent 50 and interconnecting all of the segments 51 and 56. Because of this construction, it will be seen that the stent 50 will be readily bendable along its longitudinal axis, the bending being resisted only by the relatively narrow spine 59. Furthermore, it will be understood that the individual segments 51 and 56 can be made much shorter to provide for tighter radii, or relatively long in the event the stent is not intended to be very flexible.

Though the stent 50 in FIGS. 9–12 of the drawings is not shown in conjunction with a catheter, it will be

understood by those skilled in the art that the stent will be put into place using an arrangement such as that shown in FIG. 6 of the drawings. The catheter 36 and wire channel 46 would be the same the specific stent being the only difference.

FIG. 11 of the drawings shows the cross-sectional shape of the stent 50 while the stent is held in its closed, or collapsed, condition by the pin 54. When the pin 54 is removed, the stent 50 will expand to the condition shown in FIG. 12 of the drawings. It will of course be recognized that a balloon, such as the balloon 38, may be utilized to assist in urging the walls of the stent outwardly to the desired position.

The material from which the stent 50 is made may be any of the numerous materials previously mentioned, including the material shown in FIG. 5 of the drawings. Because the stent 50 is made up of a plurality of individual segments 51 and 56, there is no particular need for additional openings in the wall of the stent, the spaces between the segments providing adequate openings for initial fluid drainage and subsequent epithelialization.

Simply by way of example, FIGS. 10 and 12 illustrate the inclusion of a filament 60 in the wall of the stent. The purpose of the filament 60 is to show that the stent 50 can be made of a plastic material having sufficient memory to be urged to the open condition as shown in FIG. 12; or, the stent 50 can be made of a relatively flaccid fabric or the like having spring filaments 60 embedded therein for urging the stent 50 to its open position. Also, the stent 50 can be made entirely of metal, including well known alloys of platinum and gold, or chromium and cobalt.

From the foregoing discussion it will be understood that the present invention provides an arterial stent and a method for placing the stent for preventing re-stenosis following angioplasty or other mechanical opening of the lumen in an artery. While several specific designs and materials have been disclosed, those skilled in the art will recognize that the materials must be implantable, and all portions of the stent must be sufficiently smooth to prevent trauma during placement. Further, all corners and the like should be well rounded to promote epithelialization without subsequent trauma due to the presence of sharp edges during natural body motions.

It will of course be understood by those skilled in the art that the particular embodiments of the invention here presented are by way of illustration only, and are meant to be in no way restrictive; therefore, numerous changes and modifications may be made, and the full use of equivalents resorted to, without departing from the spirit or scope of the invention as outlined in the appended claims.

I claim:

1. An implantable prosthesis for use in maintaining an opening within an artery, said prosthesis comprising a generally cylindrical sleeve having a wall, said wall defining a gap longitudinally thereof for allowing said sleeve selectively to assume a first position wherein said wall moves inwardly for providing a collapsed diameter of said sleeve, and a second position wherein said wall moves outwardly for providing an expanded diameter of said sleeve, means for urging said wall in one direction towards either said collapsed diameter or said expanded diameter, and locking means for preventing motion of said wall by said means for urging said wall in one direction, said one direction being outwardly towards said expanded diameter, said locking means including a plurality of lugs, at least one lug of said plurality of lugs being on each side of said discontinuity in said wall, and pin means receivable through said lugs for holding said sleeve inwardly at said collapsed diameter.

2. A prosthesis as claimed in claim 1, said lugs being so placed that said wall is overlapped when said lugs are aligned, said pin comprising a wire extending longitudinally of said sleeve and selectively movable for disengagement from said lugs.

3. A prosthesis as claimed in claim 2, and further including second locking means for fixing the diameter of said wall at said expanded diameter.

4. An implantable prosthesis for use in maintaining an opening within an artery, said prosthesis comprising a generally cylindrical sleeve having a wall, said wall defining a gap longitudinally thereof for allowing said sleeve selectively to assume a first position wherein said wall moves inwardly for providing a collapsed diameter of said sleeve, and a second position wherein said wall moves outwardly for providing an expanded diameter of said sleeve, means for urging said wall in one direction towards either said collapsed diameter or said expanded diameter, and locking means for preventing motion of said wall by said means for urging said wall in one direction, said wall having a bottom, a top diametrically removed from said bottom, and comprising a plurality of segments, a spine extending longitudinally of said sleeve along said bottom of said sleeve, each segment of said plurality of segments extending from said spine, around one side of said sleeve and to said top of said sleeve, said plurality of segments being spaced apart along each side of said spine so that said sleeve is longitudinally bendable.

5. A prosthesis as claimed in claim 4, and further including a plurality of lugs, each lug of said plurality of lugs being carried generally at said top of one segment of said plurality of segments, such that when said sleeve is moved inwardly to said collapsed diameter, said lugs are aligned, and a pin receivable through said plurality of lugs constituting said locking means.

6. A prosthesis as claimed in claim 5, said means for urging said wall in one direction including an elastic force inherent in said wall.

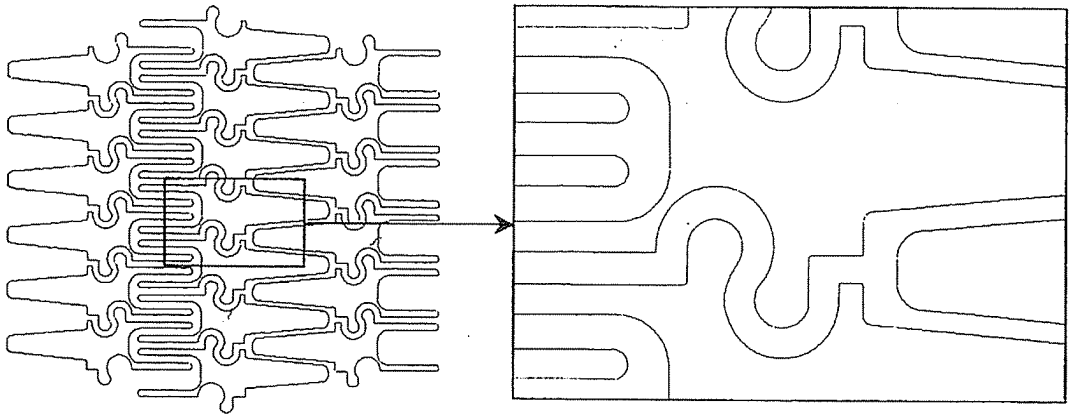
7. A prosthesis as claimed in claim 5, said means for urging said wall in one direction including spring means embedded within said wall.

* * * * *

EXHIBIT 4

Exhibit 4

Original design:



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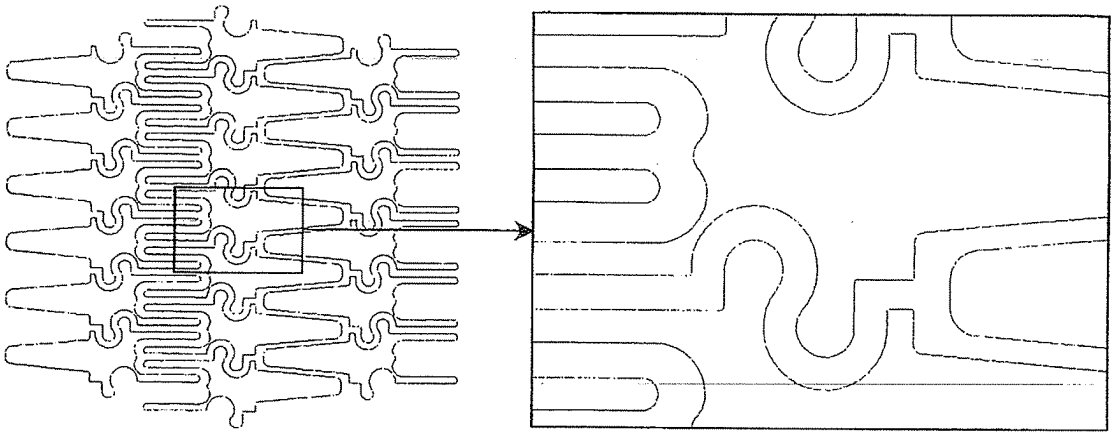

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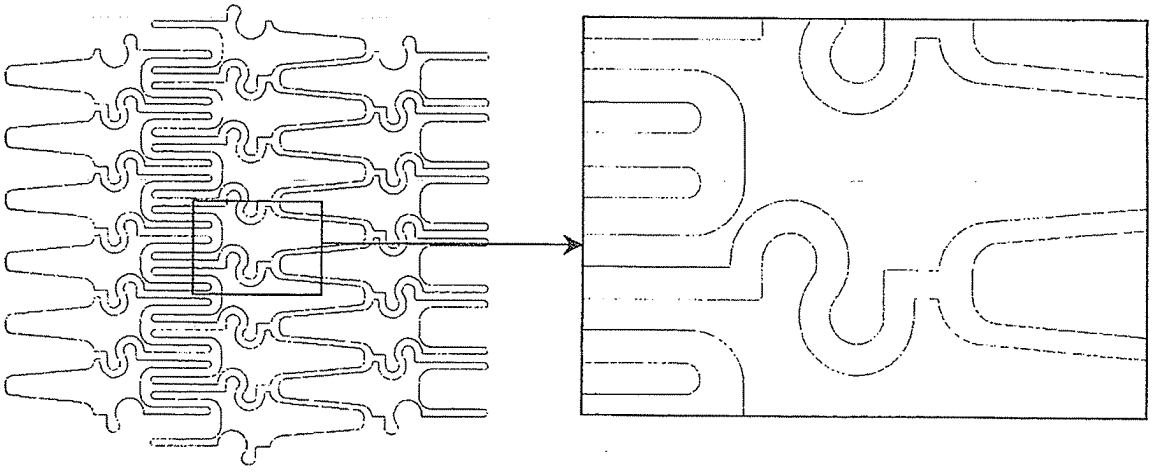
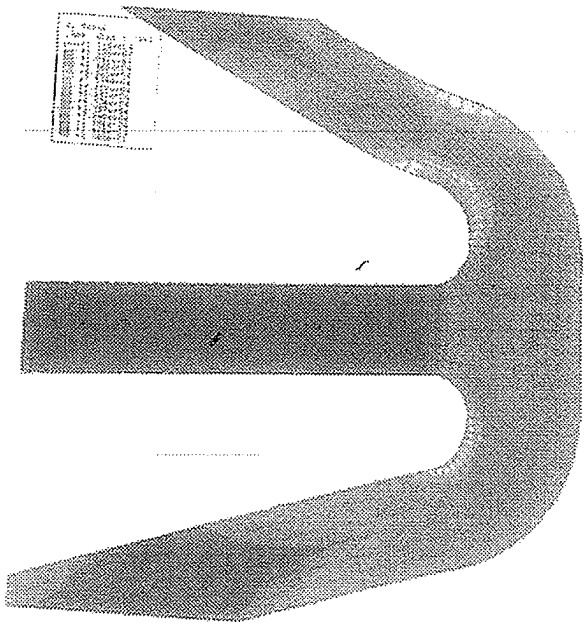
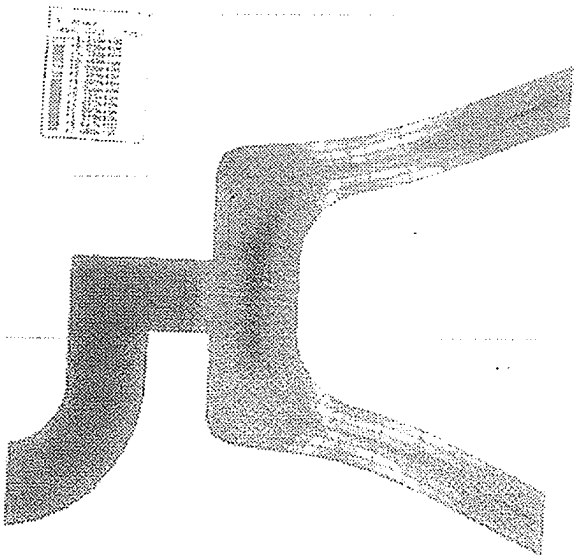


STRESS FIELDS

Original design:





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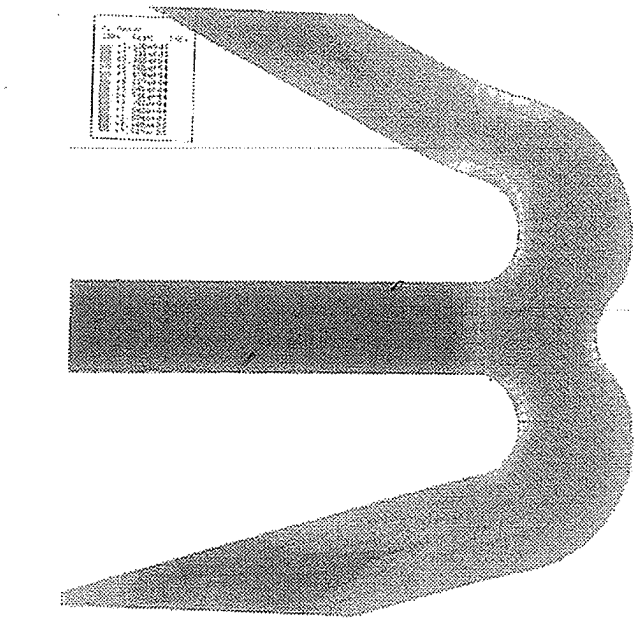
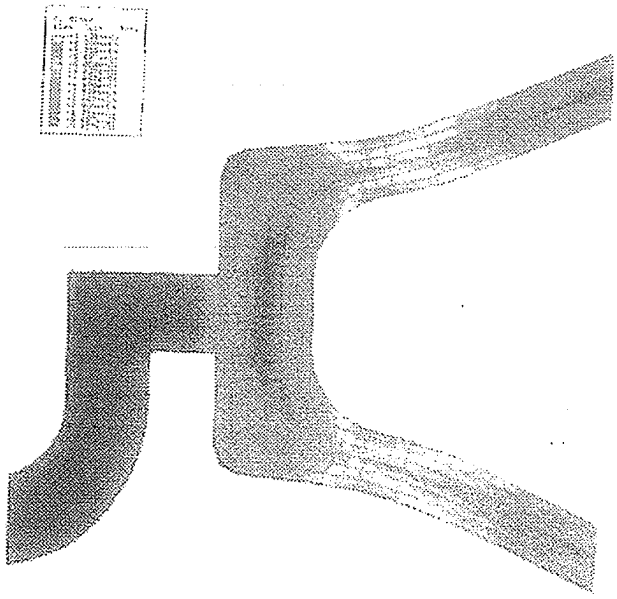
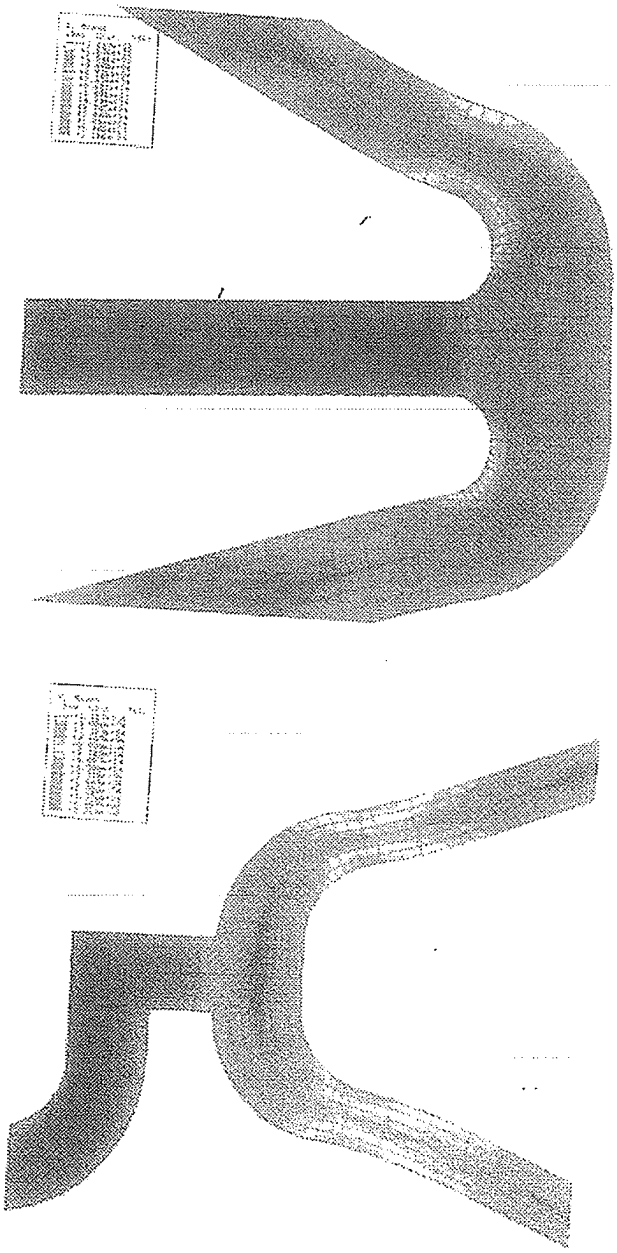
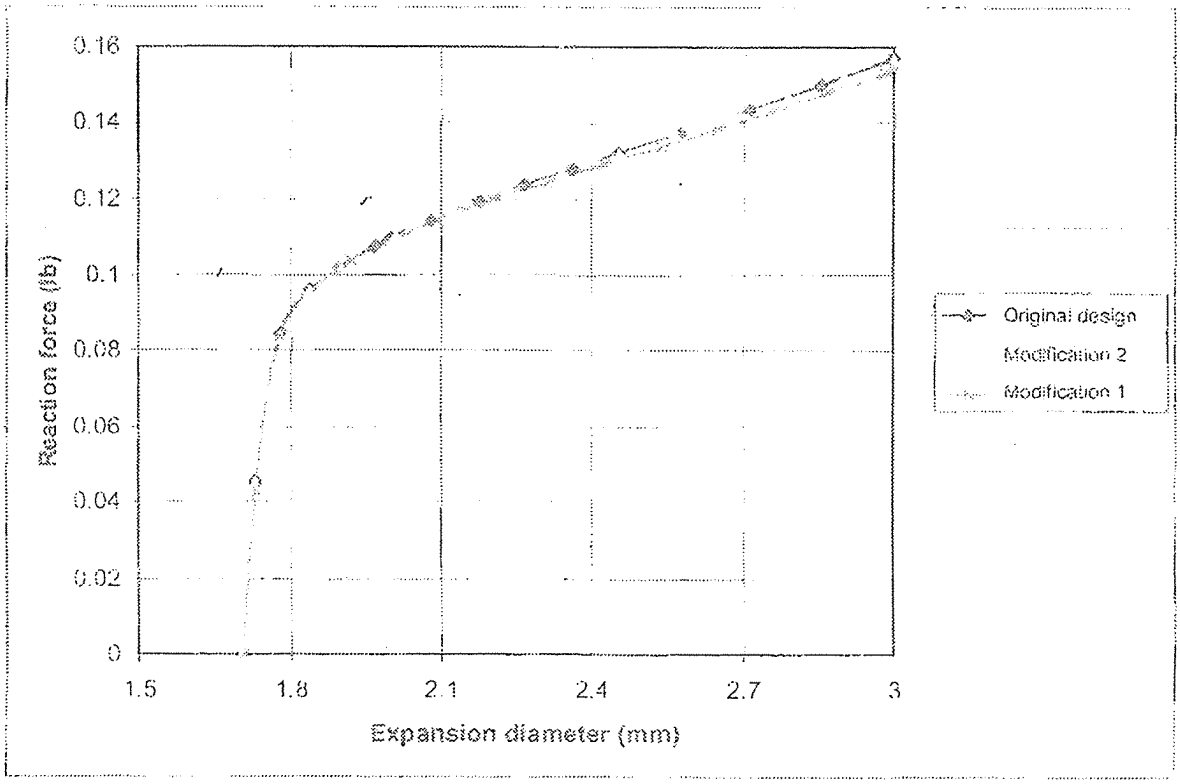




Modification 2:



GRAPH OF FORCE NEEDED TO EXPAND STENT



TABLES

TABLE 1: Reaction force (Expansion force) for 3 mm expansion

	Original design	Modification 1	Modification 2
Load (lb)	0.1570	0.1541	0.1565

TABLE 2: Maximum stress and strain in first apex region (the apex altered in Modification 1) (which is also the maximum stress/strain in the entire design)

	Original design	Modification 1	Modification 2
Max. Von Mises stress (ksi)	113.149	105.051	113.099
Max. equivalent plastic strain (in/in)	0.2240	0.1846	0.2237

TABLE 3: Maximum stress and strain in the second apex region (the apex altered in Modification 2)

	Original design	Modification 1	Modification 2
Max. Von Mises stress (ksi)	81.78	82.17	80.27
Max. equivalent plastic strain (in/in)	0.100	0.102	0.0957

United States Patent [19]

Pinchuk

[11] **Patent Number: 5,019,090**

[45] **Date of Patent: May 28, 1991**

[54] **RADIALLY EXPANDABLE ENDOPROSTHESIS AND THE LIKE**

[75] Inventor: **Leonard Pinchuk**, Miami, Fla.

[73] Assignee: **Corvita Corporation**, Miami, Fla.

[21] Appl. No.: **240,000**

[22] Filed: **Sep. 1, 1988**

[51] **Int. Cl.**[5] **A61N 29/02**; A61F 2/06

[52] **U.S. Cl.** **606/194**; 606/1; 606/108; 623/1

[58] **Field of Search** ..... 128/341, 343, 344, 840, 128/325, 303 R; 623/1; 606/191, 194, 198, 1, 106, 108

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Primary Examiner—Randall L. Green

Assistant Examiner—Stephanie L. Iantorno

Attorney, Agent, or Firm—Lockwood, Alex, FitzGibbon & Cummings

[57] **ABSTRACT**

Radially expandable endoprostheses or stents are provided, as well as their method of manufacture. These stents include a plurality of adjacent generally circumferential sections that are substantially axially positioned with respect to each other. At least one of the generally circumferential sections has a generally circumferentially disposed expandable segment that imparts circumferential and radial expandability to the stent.

20 Claims, 4 Drawing Sheets

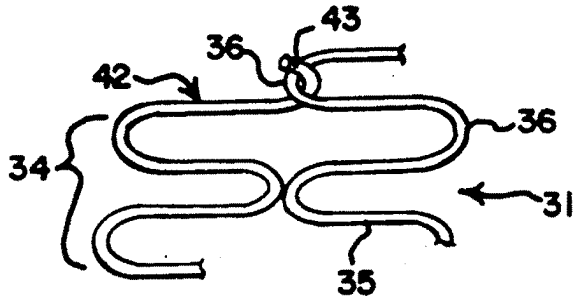


FIG_1

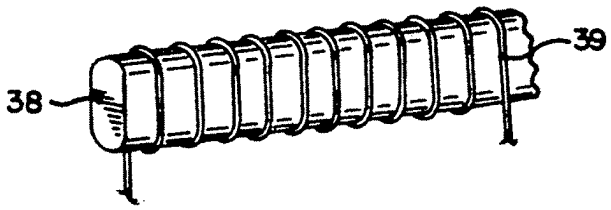


FIG_2

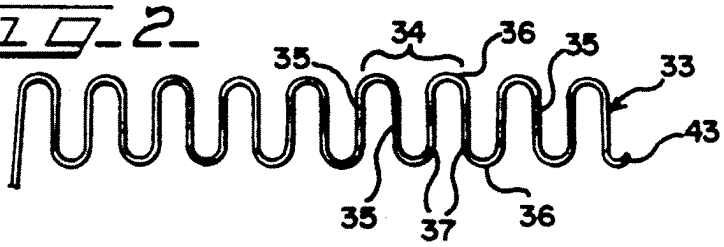


FIG_3

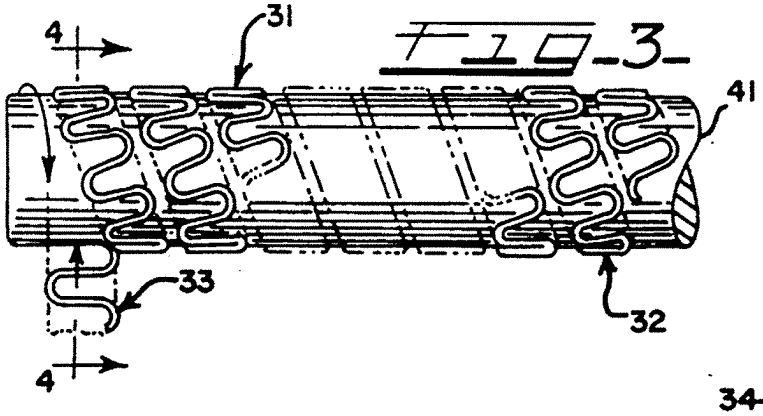


FIG_4

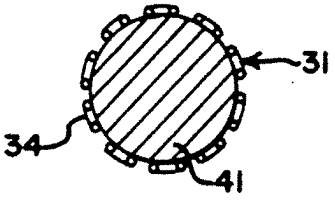


FIG_5

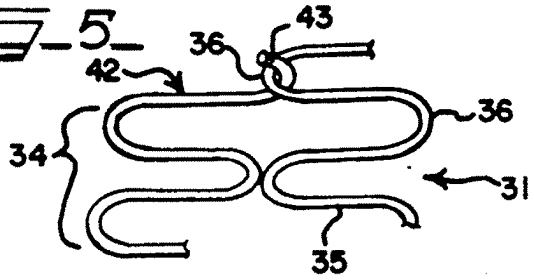


FIG_6

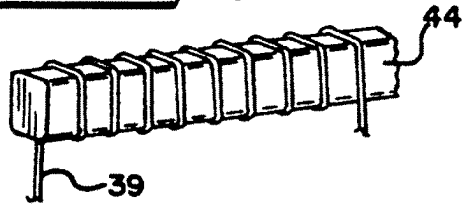


FIG_7

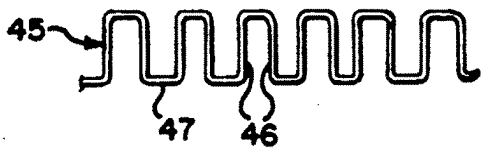


FIG. 8

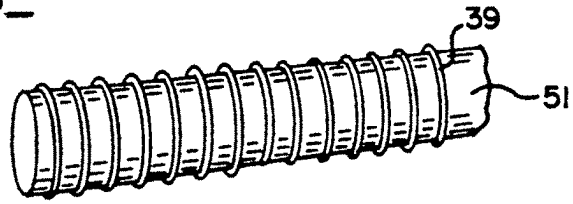


FIG. 9

FIG. 10

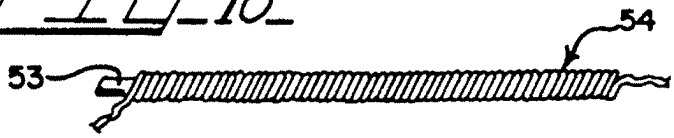


FIG. 11

FIG. 12

FIG. 13

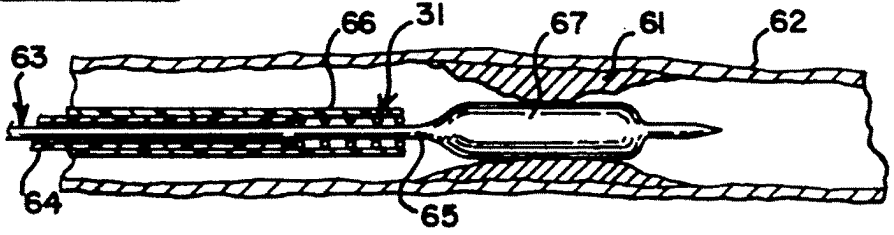


FIG_14_

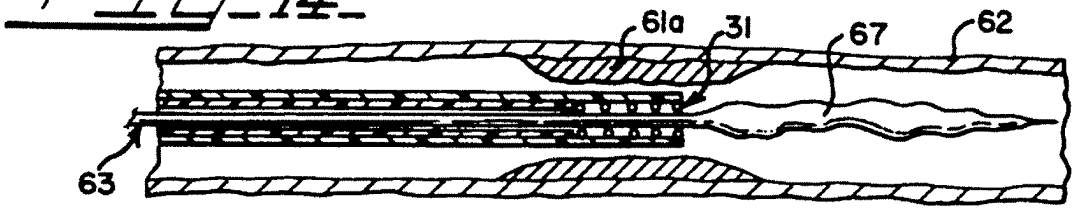


FIG_15_

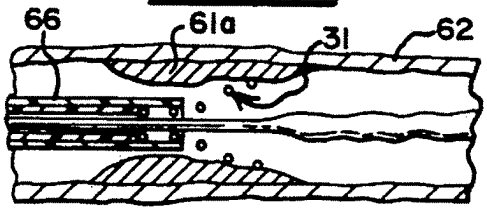


FIG_16_

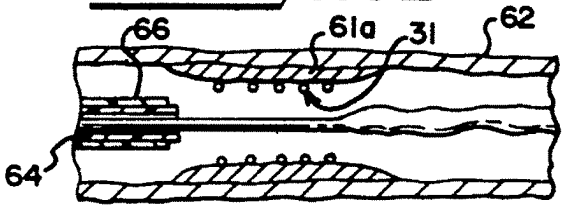


FIG_17_

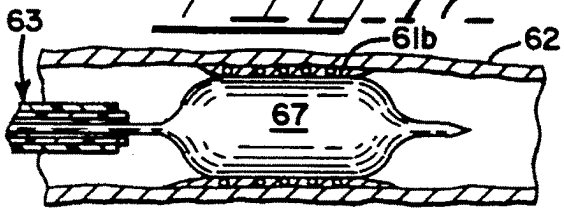
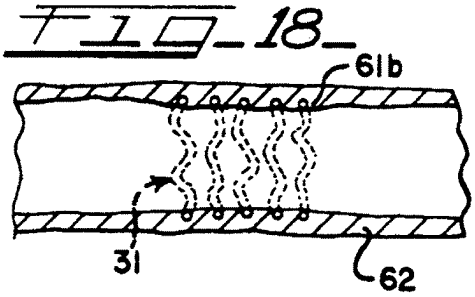


FIG_18_



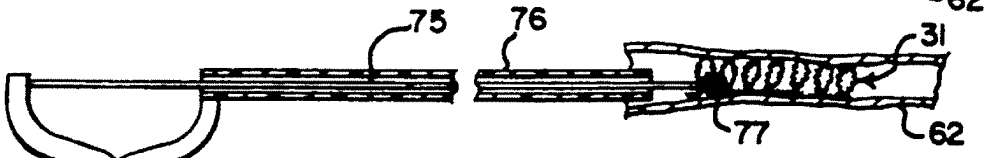
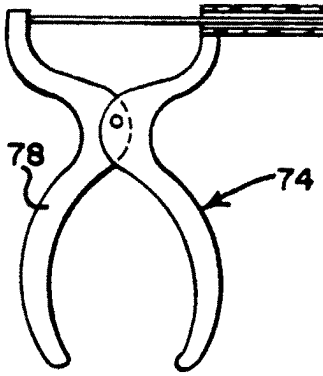


FIG_24_



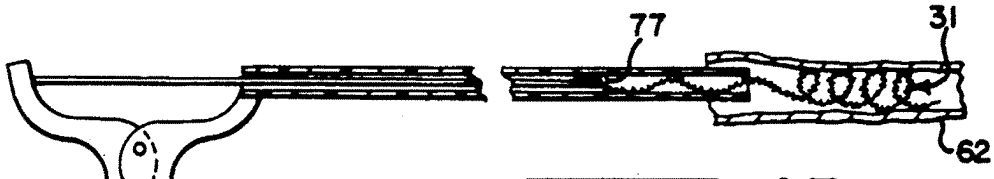
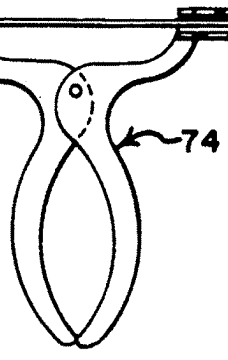


FIG_25_



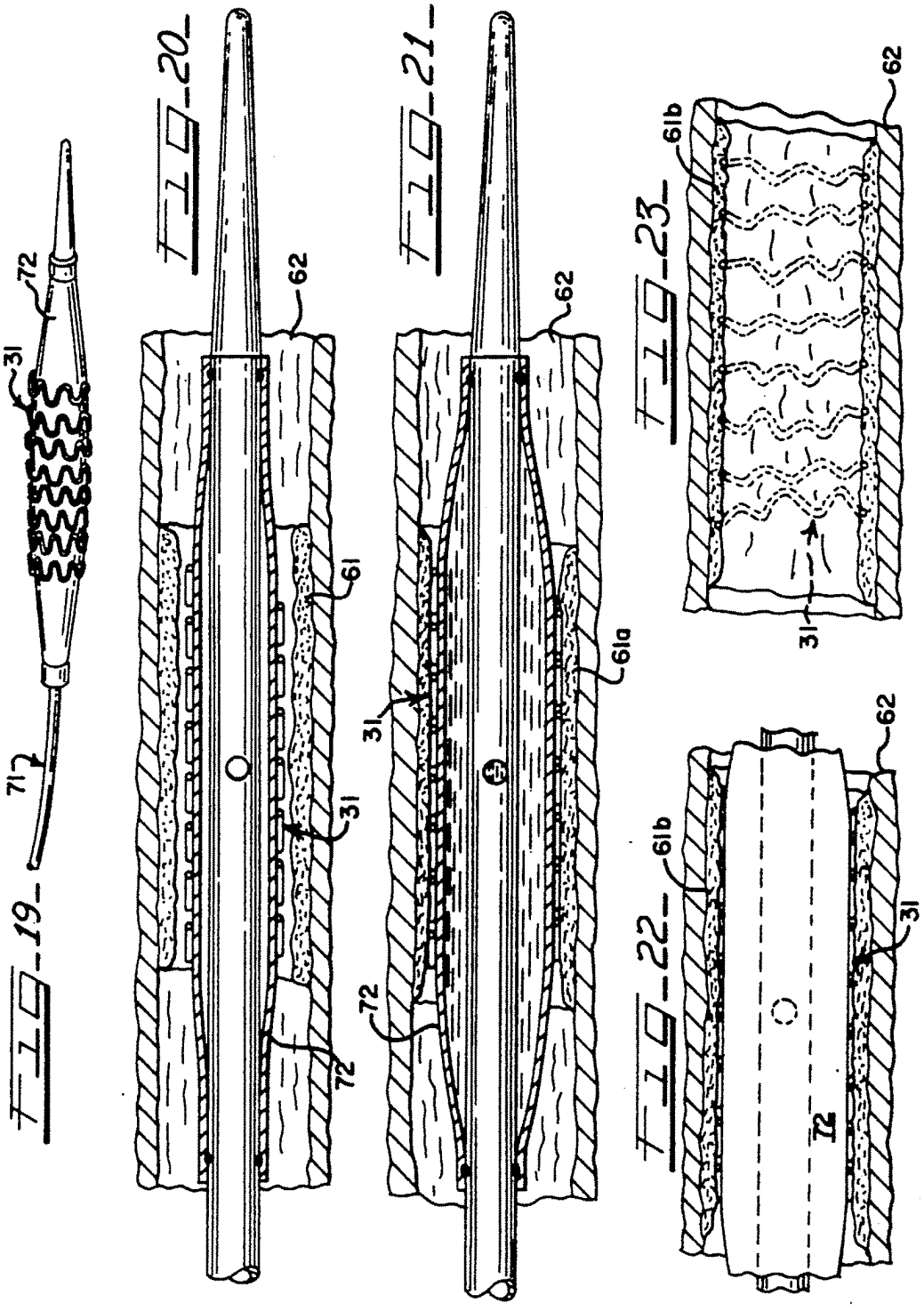


FIG-19

FIG-20

FIG-21

FIG-23

FIG-22

RADIALLY EXPANDABLE ENDOPROSTHESIS AND THE LIKE

BACKGROUND AND DESCRIPTION OF THE INVENTION

The present invention generally relates to endoprosthesis devices, to a procedure for making same, and to the use thereof. More particularly, the invention relates to a generally tubular endoprosthesis that is radially expandable between a generally unexpanded insertion circumference and an expanded implantation circumference which is greater than the unexpanded insertion circumference. Included are a plurality of generally circumferential sections, one or more of which includes one or more expandable segments that are bendable members which are generally collapsed when the endoprosthesis is in its generally unexpanded insertion orientation and which are generally opened when the endoprosthesis is in its expanded implantation orientation.

Endoprostheses are known for treating stenoses, stricture, aneurysm conditions and the like. An endoprosthesis device of this type, which is at times referred to as a stent, is typically placed or implanted by a mechanical transluminal procedure. Often a device of this type is percutaneously implanted within the vascular system to reinforce collapsing, partially occluded, weakened or abnormally dilated localized sections of a blood vessel or the like. Stents of this type can also be used in the urinary tract, the bile tract, the intestinal tract and the like. When endoprostheses or stents are used to treat a stenosis condition, typically such is done in association with a dilation element such as an angioplasty balloon. In this instance, the dilation element or balloon device opens the constriction, and a stent or the like is positioned thereat in order to prevent or at least substantially slow re-formation of the stenosis.

One attribute of a stent is that it is radially compressible and expandable so that it will easily pass through a blood vessel or the like when collapsed and will expand to its implanted size after the stenosis, aneurysm or the like has been reached. It is also desirable that a stent be generally flexible throughout its length so that it is easily maneuverable through bends and curves of the blood vessel or the like. It is typically desirable that a stent or endoprosthesis have a substantial amount of open space so as to allow for endothelialization along its length, to minimize the foreign body response, and to minimize interference with collateral blood vessels and the like. While it is important that a stent or endoprosthesis lodge securely into place at the desired location, it can be advantageous to have a stent that is removable through a transluminal percutaneous procedure, should removal be needed.

Various currently known stent products have structures that are essentially coiled springs. When this type of spring stent is tightly coiled, its diameter is relatively small for insertion through a blood vessel or the like. When the coil is sprung or coiled more loosely, the stent assumes its expanded, implantation orientation. Maass et al U.S. Pat. No. 4,553,545 is illustrative of this type of coiled spring stent or endoprosthesis. Multihelix or braided stents are also known. Stents of this general type suffer from poor maneuverability, and they are relatively thick walled and three dimensional. They are also difficult to remove once implanted, and they may exhibit numerous exposed, relatively sharp or jagged ends. Palmaz U.S. Pat. No. 4,733,665 is representative of an expandable stent of this general type. Gianturco U.S. Pat. No. 4,580,568 illustrates a percutaneous endovascular stent formed of stainless steel wire that is arranged in a closed zig-zag pattern somewhat in the nature of a bookbinder spring. Such a structure is somewhat unsymmetrical, and it may be subject to reocclusion due to the very large open space that is typically present between the wires of this type of device. Another type of stent is known as a Statz stent, and it includes a hypodermic tube with longitudinal slots etched into its body. While such a device has a high ratio of unexpanded to expanded diameter, it is a comparatively rigid, sharp-edged device which is difficult to maneuver through a tortuous path and is not easily removed in a transluminal manner.

With many of these currently known stent structures, the axial length of the stent decreases as the circumference of the stent increases, which is typically a disadvantage. For example, any such length reduction must be taken into consideration in selecting proper stent sizing for a particular implantation procedure. Also, this attribute of many prior stents requires the passage through the blood vessel or the like of a stent which is longer than the length actually needed for the implantation procedure being performed. This is a particularly difficult problem for procedures in which the stent must be passed through a pathway having twists or turns, especially for a stent structure that is not easily bendable.

The present invention avoids the various deficiencies of these types of prior art structures and provides important and advantageous features of endoprostheses or stents and the use thereof. In summary, the endoprosthesis of this invention includes a plurality of generally circumferential sections that are generally adjacent to one another along their respective opposing generally circumferential edges. At least one of these generally circumferential sections has an expandable segment that imparts radial expandability to the generally circumferential section. The expandable segment is a bendable, elbow-like member that is bendable between a generally collapsed or closed orientation and a generally opened orientation and is capable of assuming bending orientations between one that is fully closed and one that is fully opened. By this structure, the endoprosthesis or stent has an unexpanded insertion circumference and an expanded implantation circumference, which is greater than the insertion circumference. In addition, this variation in circumference is achieved without substantially changing the axial length of the endoprosthesis or stent. The stent is made by a procedure that is relatively uncomplicated, and, generally speaking, the stent can be transluminally explanted if necessary.

It is a general object of the present invention to provide an improved radially expandable, axially extending endoprosthesis of the type that can be transluminally implanted.

Another object of the present invention is to provide an improved endoprosthesis or stent that can be constructed to have very large radial expansion capabilities.

Another object of this invention is to provide an improved radially expandable axially extending endoprosthesis that is extremely maneuverable and capable of moving through a tortuous path.

Another object of the present invention is to provide an improved radially expandable axially extending endoprosthesis that can, if desired, be transluminally ex-

planted by means of, for example, a snare lead or catheter.

Another object of the present invention is to provide an improved radially expandable axially extending endoprosthesis which includes members that can be spaced apart or pointed in a manner that enhances lodging of the endoprosthesis at its implanted site.

Another object of the present invention is to provide an improved axially extending endoprosthesis that can be constructed in order to be radially expandable by an expanding member or balloon of a catheter device and/or can be radially expandable due to spring-like properties of the endoprosthesis.

Another object of this invention is to provide an improved procedure for making an axially extending and/or generally tubular endoprosthesis that is radially expandable.

Another object of the present invention is to provide an improved procedure and system for transluminally explanting an axially extending radially expandable endoprosthesis or stent.

Another object of the present invention is to provide an improved radially expandable endoprosthesis that substantially avoids the presentation of any frayed edges and that generally maintains its axial length throughout various radial expansion positions.

These and other objects, features and advantages of this invention will be clearly understood through a consideration of the following detailed description

BRIEF DESCRIPTION OF THE DRAWINGS

In the course of this description, reference will be made to the attached drawings, wherein:

FIG. **1** is a perspective view illustrating an early step in the procedure of making an endoprosthesis according to the present invention;

FIG. **2** is an elevational view illustrating a step subsequent to that shown in FIG. **1**;

FIG. **3** is an elevational view showing a manufacturing step subsequent to that of FIG. **2**, while also illustrating a substantially completed endoprosthesis in accordance with the present invention;

FIG. **4** is a cross-sectional view along the line **4—4** of FIG. **3**;

FIG. **5** is an enlarged detail view of a portion of one end of the endoprosthesis shown in FIG. **3**;

FIG. **6** is a perspective view illustrating an early step in the procedure of making another embodiment of the endoprosthesis;

FIG. **7** is an elevational view illustrating a step subsequent to that shown in FIG. **6**, while also illustrating the configuration of a portion of this endoprosthesis prior to its circumferential orientation;

FIG. **8** is a perspective view illustrating an early step in the procedure of making a further embodiment of the endoprosthesis;

FIG. **9** is an elevational view illustrating a step subsequent to that shown in FIG. **8**, while also illustrating the configuration of a portion of this endoprosthesis prior to its circumferential orientation;

FIG. **10** is an elevational view of an early step in the manufacturing procedure for still a further embodiment of the endoprosthesis;

FIG. **11** is an elevational view of a step subsequent to that shown in FIG. **10**;

FIG. **12** is an elevational view of a manufacturing step subsequent to that illustrated in FIG. **11** and which shows a length of material suitable for winding on a mandrel in a generally helical manner in order to form the endoprosthesis of this embodiment;

FIG. **13** is a generally cross-sectional view illustrating an early step in a procedure for implanting an endoprosthesis according to the present invention, this particular procedure being especially suitable for an endoprosthesis having spring-like properties;

FIG. **14** is a generally cross-sectional view illustrating an implantation step subsequent to that shown in FIG. **13**;

FIG. **15** is a generally cross-sectional view illustrating an implantation step subsequent to that of FIG. **14**;

FIG. **16** is a generally cross-sectional view illustrating an implantation step subsequent to that illustrated in FIG. **15**;

FIG. **17** is a generally cross-sectional view of an implantation step subsequent to that illustrated in FIG. **16**;

FIG. **18** is a generally cross-sectional view of an implanted stent or endoprosthesis in accordance with the present invention;

FIG. **19** is an elevational view of an endoprosthesis and distal end of a balloon catheter for an implantation procedure that is especially suitable for an endoprosthesis according to the present invention that is constructed of a malleable-type of material;

FIG. **20** is a generally cross-sectional illustration of the endoprosthesis and catheter of FIG. **19** positioned within a blood vessel;

FIG. **21** is a generally cross-sectional illustration of an implantation stage subsequent to that shown in FIG. **20**;

FIG. **22** is a generally cross-sectional illustration of an implantation stage subsequent to that shown in FIG. **21**;

FIG. **23** is a generally cross-sectional illustration of an implanted stent or endoprosthesis according to the present invention;

FIG. **24** is a generally cross-sectional illustration of a snare catheter shown explanting a stent or endoprosthesis in accordance with the present invention; and

FIG. **25** is a generally cross-sectional illustration showing a further stage of the explantation procedure illustrated in FIG. **24**.

DESCRIPTION OF THE PARTICULAR EMBODIMENTS

A radially expandable axially extending endoprosthesis or stent is generally designated as **31** in FIG. **3**, as well as in FIG. **4**. The stent includes a plurality of generally circumferential sections **32**. In this illustrated embodiment, each of the circumferential sections **32** are formed from the same continuous, helically wrapped length, such as the undulating length **33** shown in FIG. **2**.

At least one of the circumferential sections **32** includes at least one expandable segment **34**. Expandable segment **34** is a bendable member that typically includes one or more legs **35**. Each leg **35** is bendably secured to the rest of the circumferential section **32** by a so-called living joint or hinge that is a unitary or integral component of the leg **35** and the adjacent portion of the circumferential section **32**. For example, in the embodiment illustrated in FIGS. **1** through **5**, each leg **35** is bendably joined to another leg **35** through an integral or living hinge **36** which has a generally arcuate shape. When the stent **31** expands, the integral hinge **36** permits end portions **37** of the legs **35** to move farther apart, thereby increasing the circumference and diameter of the stent **31**. Of course, the circumference and

diameter of the stent **31** can be reduced by forces which move these end portions **37** closer to each other.

An understanding of the manner in which the endoprostheses according to this invention, such as the stent **31**, can be made will be obtained from a consideration of FIGS. **1**, **2** and **3**. FIG. **1** shows a mandrel **38** that has a cross-sectional configuration that is somewhat oval in shape. Mandrel **38** can, for example, be a circular tube or rod that has been flattened on two opposing longitudinal portions in order to provide a cross-section that is generally rectangular in shape, with two opposing end portions thereof being arcuate or rounded. The mandrel is preferably composed of a malleable metal such as copper of the like.

A strand **39** of wire or other material, as generally discussed elsewhere herein, is generally tightly wound over the mandrel to the extent that the strand **39** takes on a cross-sectional shape along the lines of that of the mandrel **38**. Preferably, this winding is done in a manner such that there is a substantial spacing between each individual wind of the strand **39**. Generally speaking, the tighter the wind and the thinner the mandrel, the closer will be the spacing between the expandable segments **34** of the completed stent **31**. After this winding has been completed, the wound strand **39** on the mandrel **38** is preferably heat annealed using a conventional annealing process for the type of wire used.

After this winding and annealing procedure has been completed, the mandrel **38** is removed from the wound strand **39**. Removal of the wound strand is facilitated by axially stretching the malleable mandrel to effectively reduce its diameter. The wound strand **39** is then subjected to flattening forces so that the three-dimensional wound strand **39** is transformed into a generally planar shape such as that of the undulating length **33** shown in FIG. **2**. These forces may be applied by any suitable means. For example, the wound strand **39** can be compressed between two planar surfaces, during which procedure, portions of the wound strand **39** are twisted until the generally uni-planar undulating length **33** is formed. This length has a generally sinusoidal character.

In order to complete formation of the stent **31** illustrated in FIG. **3**, the undulating length **33** is then wound, in a generally helical manner, around a substantially cylindrical mandrel **41**, as is generally illustrated in FIG. **3**. This generally helical wrapping procedure continues until the desired number of circumferential sections are formed in order to provide a stent **31** of a desired length. It may, depending upon the type of wire used, be necessary to heat anneal the helical winding of FIG. **3**.

With reference to FIG. **5**, this winding procedure that is generally illustrated in FIG. **3** includes proceeding in a manner so as to avoid the presentation of any loose ends in the completed stent **31**. This is readily accomplished by forming the strand **39** and the undulating length **33** so that each end circumferential section **42** has a free end **43** that readily hooks onto an adjacent portion of the stent **31**, such as an integral hinge **36** of the circumferential section **32** that is adjacent to and inwardly spaced from the end circumferential section **42**. The free end **43** illustrated in FIG. **5** is in the nature of a hook portion that readily loops or tucks into the integral hinge **36**. It may be desirable in some embodiments to weld this hook to hinge **36**.

Regarding the embodiment shown in FIGS. **6** and **7**, the mandrel around which the strand **39** is wound is a substantially rectangular mandrel **44**. As a result, the generally planar structure that is subsequently formed is an undulating length **45** that includes a plurality of legs **46** joined by a unitary or integral hinge or living hinge **47** that is typically less arcuate than the integral hinge **36**. This undulating length **45** is then formed into an endoprosthesis or stent by helically winding same on a structure such as the cylindrical mandrel **41**.

Another embodiment of the endoprosthesis or stent is made in a manner generally illustrated in FIGS. **8** and **9**. Here, the mandrel is a generally lens-shaped mandrel **51** which has a transverse cross-section that can be described as defining two convex surfaces positioned in back-to-back relationship with each other. Much in the same manner as the other embodiments, the elongated strand **39** is wound around the lens-shaped mandrel **51** and then preferably heat annealed. The mandrel **51** is subsequently moved therefrom, and the wound strand **39** is rendered substantially uni-planar in order to form undulating length **52** that is suitable for forming into a stent by wrapping around the mandrel **41**.

Another embodiment illustrating the manufacture of an endoprosthesis or stent in accordance with this invention is generally illustrated in FIGS. **10**, **11** and **12**. A strand is wound around a small-diameter mandrel **53** which is circular in cross-section. In this case, the strand is formed into a tightly wound helix **54**. Thereafter, the mandrel **53** is removed, and the strand is formed into a more loosely wound helix **55**. For example, the helix **55** can be elongated such that the pitch angle is less than approximately 60°. This helix **55** is then flattened generally in the manner previously discussed, for example to **10** tons in a pneumatic press, in order to form a generally uni-planar undulating length **56**. If desired, the length **56** can be axially compressed in a contained mold to the desired pitch angle. Length **56** is suitable for winding around cylindrical mandrel **41** in order to thereby form an endoprosthesis or stent.

Stents illustrated herein are typically capable of moving through a tortuous path that may be encountered in vascular system implantation. Such stents can be easily axially bent over a relatively small radius without damage or high bending resistance.

It should be appreciated that in the illustrated embodiments, each circumferential section **32** is generally identical. It is also possible within the spirit of the invention to provide circumferential sections that are not this uniformly shaped. For example, the circumference of adjacent sections can differ in order to form a stent that is not strictly shaped in the nature of a right cylinder. For example, tapered, truncated cone-shaped stents or stepped stents can be provided. In addition, in some applications, it can be suitable to include circumferential sections that are not composed entirely of expandable segments, but instead could include non-expandable portions that are joined by expandable segments. It also may be possible to provide stents within the spirit of the present invention which include one or more circumferential sections that form a stent device without proceeding with helical winding around cylindrical mandrel **41** or the like.

It is also possible to provide a stent that has a generally bifurcated structure for use in situations in which the stenosis, aneurysm or the like that is to be treated is at a branching location within the vascular system or the like. Such a bifurcated stent structure can be formed, for example, by joining portions of the opposing ends of two different unitary stents in order to pro-

vide a total structure that is bifurcated, Y-shaped or the like. It should also be appreciated that the stent can be composed of a plurality of helical strands in a parallel or antiparallel configuration.

The materials out of which stents according to the present invention can be made, and especially the expandable segments thereof, fall into two general categories. The material can be either elastic or generally inelastic. Examples of elastic materials include spring steels, stainless steel, Nitinol, Elgiloy, an alloy known as NP36N, and the like. Generally inelastic materials can be characterized as being malleable. Included are tantalum, titanium, silver, gold, and annealed versions of the elastic materials described herein. Polymers may also be used, such as polyether sulfone, polyimide, polycarbonate, polypropylene, ultra high molecular weight polyethylene, carbon fiber, Kevlar, and the like. It is also possible to coat these materials with porous or textured surfaces for cellular ingrowth and the like or with nonthrombogenic agents such as pyrolytic carbon, heparin, hydrogels, Teflon materials, silicones, polyurethanes and the like. The stents can be treated so that drugs can be eluted therefrom. It is also possible that certain stents may be made of biodegradable materials. In any event, the stent material, of course, is to be biocompatible. It should also be appreciated that the strand of stent material can be round in cross-section as is typical of wires, or it can be flat or rectangular in cross-section, for example.

FIGS. 13 through 18 illustrate an implantation procedure and an insertion system that is particularly suitable for stents that are constructed of an elastic material such as spring steel. A stenosis or lesion 61 is shown within a blood vessel 62. The stent 31 is positioned on a balloon catheter, generally designated as 63. An introducer tube or plunger 64, or a similar stop-providing structure, is positioned along the outside surface of the catheter tube 65. The stent 31 is located distally of the member 64, and a sheath 66 holds the stent 31 in a generally compressed state during which the expandable segments of the stent 31 are generally collapsed or closed. FIG. 13 further shows the balloon 67 of the catheter in a mode in which it is exerting outwardly radially directed forces on the lesions in order to dilate same to provide a wider opening as generally illustrated in FIG. 14 in order to thereby generally reduce the overall extent of the lesion to the general configuration of initially treated lesion 61*a*. At this time, the balloon 67 is collapsed, and the catheter 63 is moved in a distal direction so that the collapsed stent 31 is generally positioned within the lesion 61*a*. Next, as illustrated in FIG. 15, the sheath 66 is withdrawn by moving same in a generally proximal direction, and the stent 31 is released from the sheath 66. This release can be such that adjacent circumferential sections of the stent expand in a generally sequential manner, which is generally illustrated in FIG. 15.

After this procedure is completed, the entire stent 31 has been sprung, and it springingly engages the dilated lesion 61*a*, which is generally illustrated in FIG. 16. Thereafter, as seen in FIG. 17, the catheter 63 can be moved in a generally proximal direction until the balloon 67 is again generally aligned with the dilated lesion 61*a*, as desired. Then, the balloon 67 can be pressurized in order to further implant the stent 31 and in order to further dilate the lesion as desired so as to form a treated lesion 61*b* which remains after the catheter 63 is removed, as is generally shown in FIG. 18.

FIGS. 19 through 23 show an arrangement that is especially suitable for non-elastic stents in which the expandable segments thereof are made of malleable material. With reference to FIGS. 19 and 20, a stenosis or lesion 61 within blood vessel 62 is transluminally reached by a balloon catheter 71 having a stent 31 overlying the collapsed balloon 72 of the catheter 71. The balloon 72 is then expanded in a well-known manner, at which time the stent 31 is also expanded by opening the expandable segments thereof. An intermediate dilation position is shown in FIG. 21, and an initially dilated lesion 61*a* is shown therein. FIG. 22 shows additional dilation by the balloon 72, and the thus treated lesion 61*b* is also shown. After this stage is achieved, the balloon catheter 71 is removed, as shown in FIG. 23.

The stent 31 remains in place as generally illustrated in FIG. 23 because the malleable material (or for that matter an elastic material) exerts a hoop stress when it is expanded to the size illustrated in FIG. 23 such that it will not collapse by inwardly directed radial forces presented by the treated lesion and vessel wall or the like. In other words, the hoop stress of the expanded stent is greater than the hoop forces exerted by the passageway within which the stent is implanted. In addition, the force required to open the collapsed stent by the balloon is less than the hoop force provided by the balloon. In other words, the hoop stress of the collapsed or unextended stent is less than that of the hoop force provided by the pressurized balloon of the catheter. One feature that can contribute to the advantageous hoop stress properties of the malleable stents of the type illustrated in the drawings is the ability of the stent to expand well beyond that needed to effect the dilation procedure. For example, a typical dilation procedure and stent extension is one in which the fully extended dilating diameter or circumference is approximately three times the insertion or collapsed diameter or circumference. With stent structures such as those illustrated in the drawings, the amount of possible expansion can be on the order of two to twenty times, depending upon the length of each undulation and the distance between the legs. This feature, together with the malleability of the particular material utilized, tends to reduce the hoop force that is needed to expand the stent to about three times its insertion or collapsed configuration.

FIGS. 24 and 25 illustrate a stent withdrawal procedure and a snare catheter system that can be used to remove or explant implanted stents according to the present invention. A snare catheter, generally designated as 74, is illustrated. An elongated member 75 is slidably positioned within a catheter body 76. Elongated member 75 includes a hook member 77 at its distal end. When extended into the stent 31, the hook member 77 snares a portion of the stent 31. A suitable control structure, such as the puller assembly 78 illustrated is manipulated in order that the hook member moves in a proximal direction, with the result that the stent begins to uncoil and is opened to such an extent that it can be passed through the blood vessel 62 or the like until it is totally removed from the body by continued movement of the elongated member 75 in the proximal direction.

For purposes of illustration, the following details are given regarding a typical stent 31. An exemplary malleable material is tantalum wire having a diameter of 0.005 inch wound on a mandrel having a nominal diameter of 0.020 inch. The length of each leg 46 is on the order of about 0.048 inch, and the center-to-center spac-

ing between adjacent integral or living hinges **36** is about 0.010 inch. A typical collapsed or insertion outer diameter for such a stent is about 0.085 inch, with the inner diameter thereof being about 0.075 inch. The overall length of the stent **31** is selected to be that generally needed to treat the lesion or the like inasmuch as the overall length of the stent will remain substantially the same whether it is collapsed or extended, except to the degree that the legs **46** of the exterior circumferential sections **32** move somewhat inwardly as the hinge is flexed, thereby somewhat nominally decreasing the overall length of the stent. A typical expanded diameter is 0.240 inch outside diameter with 0.230 inch inside diameter. The expansion ratio is approximately 2.8 in this representative device.

It will be understood that the embodiments of the present invention which have been described are illustrative of some of the applications of the principles of the present invention. Numerous modifications may be made by those skilled in the art without departing from the true spirit and scope of the invention.

I claim:

1. A radially expandable endoprosthesis, comprising:

a plurality of generally circumferential sections, including end and intermediate generally circumferential sections, said end and intermediate generally circumferential sections being substantially adjacent to one another and generally parallel to each other in order to thereby generally defined an endoprosthesis having a longitudinal axis along which each of said generally circumferential sections are axially spaced;

each of said generally circumferential sections includes an expandable segment that imparts radial expandability to said generally circumferential section whereby said section has an unexpanded insertion circumference and an expanded implantation circumference which is greater than said unexpanded insertion circumference;

said expandable segment of each generally circumferential section is a generally foldable member that is bendable between a generally closed orientation and a generally opened orientation so as to impart radial expandability to the generally circumferential section;

said generally circumferential sections form a continuous helix that defines an axially extending endoprosthesis; wherein said end sections each include a free end; and

means for engaging the free end of each of said end sections with an adjacent one of said intermediate generally circumferential sections, thereby avoiding the presentation of loose ends on the endoprosthesis.

2. The endoprosthesis according to claim **1**, wherein said foldable member includes a generally elbow-like member.

3. The endoprosthesis according to claim **1**, wherein said foldable member includes a pair of legs unitarily connected together at a bendable portion.

4. The endoprosthesis according to claim **1**, wherein said generally circumferential sections form a substantially cylindrical endoprosthesis.

5. The endoprosthesis according to claim **1**, wherein said expandable segment is a malleable member, and wherein the expanded implantation circumference is achieved by radially directed forces from an expandable element of a catheter.

6. The endoprosthesis according to claim **1**, wherein each of said generally foldable members has a pair of legs joined by a substantially U-shaped portion, and alternating ones of said substantially U-shaped portions are substantially oppositely oriented.

7. The endoprosthesis according to claim **1**, wherein said generally foldable member is substantially V-shaped.

8. The endoprosthesis according to claim **1**, wherein each of said generally foldable members has a pair of legs joined by a substantially V-shaped portion, and alternating ones of said substantially V-shaped portions are substantially oppositely oriented.

9. The endoprosthesis according to claim **1**, wherein said endoprosthesis is generally tubular, and respective circumferential edges of respective generally circumferential sections are generally adjacent to each other.

10. The endoprosthesis according to claim **1**, wherein said expandable segment of each generally circumferential section had been formed by winding a strand on a shaped mandrel to form a wound strand which was subsequently flattened to a generally uni-planar configuration, and wherein said generally uni-planar wound strand was subsequently wrapped around another mandrel and removed therefrom to thereby provide said radially expandable endoprosthesis.

11. The endoprosthesis according to claim **1**, wherein each of said generally foldable members has a pair of legs joined at substantially right angles at opposite ends of a substantially straight section in order to thereby define generally right-angled zig-zag structure.

12. A radially expandable endoprosthesis, comprising:

a plurality of generally circumferential sections, including end and intermediate generally circumferential sections, said end and intermediate generally circumferential sections being substantially adjacent to one another and generally parallel to each other in order to thereby generally define an endoprosthesis having a longitudinal axis along which each of said generally circumferential sections are axially spaced;

each of said generally circumferential sections includes an expandable segment that imparts radial expandability to said generally circumferential section whereby said section has an unexpanded insertion circumference and an expanded implantation circumference which is greater than said unexpanded insertion circumference;

said expandable segment of each generally circumferential section is a generally foldable member that is bendable between a generally closed orientation and a generally opened orientation so as to impart expandability to the generally circumferential section;

said generally circumferential sections form a continuous helix that defines an axially extending endoprosthesis; wherein said end sections each have a free end; and

hook means for engaging the free end of each of said end portions to an adjacent one of said intermediate generally circumferential sections, thereby avoiding the presentation of loose ends on the endoprosthesis.

13. The endoprosthesis according to claim **12**, wherein said generally foldable member is substantially U-shaped.

14. A radially expandable endoprosthesis assembly, comprising:

a plurality of generally circumferential sections, including end and intermediate generally circumferential sections, said end and intermediate generally circumferential sections being substantially adjacent to one another and generally parallel to each other in order to thereby generally define an endoprosthesis having a longitudinal axis along which each of said generally circumferential sections are axially spaced;

each of said generally circumferential sections includes an expandable segment that imparts radial expandability to said generally circumferential section whereby said section has an unexpanded insertion circumference and an expanded implantation circumference which is greater than said unexpanded insertion circumference;

said expandable segment of each generally circumferential section is a generally foldable elastic spring-like member that is bendable between a generally closed orientation and a generally opened orientation so as to impart radial expandability to the generally circumferential section;

said generally circumferential sections form a continuous helix that defines an axially extending endoprosthesis; wherein said end section each have a free end; and

means for engaging the free end of each of said end sections with an adjacent one of said intermediate generally circumferential sections, thereby avoiding loose ends on the endoprosthesis; and

further including overlying sheath means for maintaining the unexpanded insertion circumference of the endoprosthesis in opposition to outwardly directed generally radial forces imparted by said elastic spring-like member onto an inside surface of the sheath means until said spring-like member is removed from the sheath to obtain said expanded implantation circumference.

15. An implantable and explantable endoprosthesis system, comprising a radially expandable axially extending endoprosthesis and a device for transluminally explanting the endoprosthesis; said endoprosthesis includes:

a plurality of generally circumferential sections, including end and intermediate generally circumferential sections being substantially adjacent to one another and generally parallel to each other in order to thereby generally define an endoprosthesis having a longitudinal axis along which each of said generally circumferential sections are axially spaced,

each of said generally circumferential sections includes an expandable segment that imparts radial expandability to said generally circumferential section whereby said section has an unexpanded insertion circumference and an expanded implantation circumference which is greater than said unexpanded insertion circumference,

said expandable segment of each generally circumferential section is a generally foldable member that is bendable between a generally closed orientation and a generally opened orientation so as to impart expandability to the generally circumferential section,

said generally circumferential sections form a continuous helix that defines an axially extending endoprosthesis; wherein said end sections each have a free end;

means for engaging the free end of each of said end sections with an adjacent one of said intermediate generally circumferential sections, thereby avoiding loose ends on the endoprosthesis; and

said device for transluminally explanting the endoprosthesis includes:

a catheter member that is percutaneously insertable into a blood vessel or the like within which said endoprosthesis has been radially expanded and implanted,

an elongated member slidably mounted within said catheter member, said elongated member having a proximal portion exterior of the body,

snaring means at a distal end of the elongated member, said snaring means having a size whereby it slidably passes through said catheter member,

means for manipulating a proximal portion of the elongated member from a location exterior of the body, said manipulating means facilitating engagement of said snaring means with one of said circumferential sections of the implanted endoprosthesis,

puller means for sliding the elongated member and the snaring means in a proximal direction within said catheter member by moving the body-exterior proximal portion of the elongated member in a direction away from the endoprosthesis, and

said puller means further being for at least partially uncoiling said helix and for reducing the radial size of the endoprosthesis to less than said expanded implantation circumference and such that it will pass through the catheter member and from the body, whereby the endoprosthesis of reduced radial size has been fully explanted.

16. The system according to claim 15, wherein each of said generally foldable members has a pair of legs and a foldable portion, and alternating ones of said foldable portions are substantially oppositely oriented.

17. The system according to claim 1, wherein said foldable member of the endoprosthesis includes a generally elbow-like member.

18. The system according to claim 15, wherein said foldable member of the endoprosthesis includes a pair of legs unitarily connected together at a bendable portion.

19. The system according to claim 15, wherein said expandable segment of the generally circumferential section of the endoprosthesis had been formed by winding a strand on a shaped mandrel to form a wound strand, said wound strand having been subsequently flattened, and said circumferential section is defined by said flattened wound strand in that said flattened wound strand was subsequently wrapped around a mandrel and removed therefrom to thereby provide said radially expandable endoprosthesis.

20. An implantable and explantable endoprosthesis system, comprising a radially expandable axially extending endoprosthesis and a device for transluminally explanting the endoprosthesis; said endoprosthesis includes:

a plurality of generally circumferential sections, including end and intermediate generally circumferential sections, said end and intermediate generally circumferential sections being substantially adjacent to one another and generally parallel to each other in order to thereby generally define an endoprosthesis having a longitudinal axis along which

each of said generally circumferential sections are axially spaced,

each of said generally circumferential sections includes an expandable segment that imparts radial expandability to said generally circumferential section whereby said section has an unexpanded insertion circumference and an expanded implantation circumference which is greater than said unexpanded insertion circumference,

said expandable segment of each generally circumferential section is a generally foldable member that is bendable between a generally closed orientation and a generally opened orientation so as to impart radial expandability to the generally circumferential section,

said generally circumferential sections form a continuous helix that defines an axially extending endoprosthesis; wherein said end sections each have a free end, and

means for engaging the free end of each of said end sections with an adjacent one of said intermediate generally circumferential sections, thereby avoiding the presentation of loose ends on the endoprosthesis; and

said device for transluminally explanting the endoprosthesis includes:

an elongated member that is percutaneously insertable into a blood vessel or the like within which said endoprosthesis has been radially expanded and implanted, said elongated member having a proximal portion exterior of the body,

snaring means at a distal end of the elongated member,

means for manipulating a proximal portion of the elongated member from a location exterior of the body, said manipulating means facilitating engagement of said snaring means with one of said circumferential sections of the implanted endoprosthesis,

puller means for sliding the elongated member in a proximal direction by moving the body-exterior proximal portion of the elongated member in a direction away from the endoprosthesis,

said puller means further being for at least partially uncoiling said helix and for reducing the radial size of the endoprosthesis to less than said expanded implantation circumference and such that said endoprosthesis will pass through the blood vessel or the like, and

means for completely removing the elongated member from the body until the endoprosthesis of reduced radial size has been fully explanted.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,019,090

DATED : May 28, 1991

INVENTOR(S) : Leonard Pinchuk

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 5, line 14, "of" should read --or--.

Col. 9, line 29, "defined" should read --define--.

Col. 11, line 27, "section" should read --sections--; line 48, after "sections" insert --; said end and intermediate generally circumferential sections--.

Col. 12, line 41, "1," should read --15,--.

Signed and Sealed this

Second Day of November, 1993

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

US005397355A

United States Patent [19]

Marin et al.

[11] Patent Number: 5,397,355

[45] Date of Patent: Mar. 14, 1995

[54] INTRALUMINAL STENT

[75] Inventors: **Michael L. Marin; Ralph Marin,** both of New York, N.Y.

[73] Assignee: **Stentco, Inc.,** Elmwood Park, N.J.

[21] Appl. No.: **278,546**

[22] Filed: **Jul. 19, 1994**

[51] **Int. Cl.**[6] **A61F 2/04**

[52] **U.S. Cl.** **623/12**

[58] **Field of Search** 623/1, 11, 12; 606/191-200, 151-158; 411/74, 71, 61; 138/108, 112

[56] **References Cited**

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Primary Examiner—David Isabella

Assistant Examiner—Debra S. Brittingham

Attorney, Agent, or Firm—Darby & Darby

[57] **ABSTRACT**

An improved stent provides mechanical anchoring of the stent to a blood or other body vessel. The stent has, in a preferred embodiment, barbs which remain within the surface of the stent when the stent is in its unexpanded condition, but which extend from the surface of the stent when the stent is expanded. These barbs are adapted to engage, for example, a graft and/or the inner layers of a blood vessel to mechanically attach the stent to the vessel. Because friction is not solely relied upon to hold the stent in place, the stent may exert less force on the blood vessel which, in turn, means that a thinner stent requiring less force for expansion may be used. In addition, there may be less radial force permanently exerted in an artery after stent deployment which may be less injurious to the vessel.

6 Claims, 1 Drawing Sheet

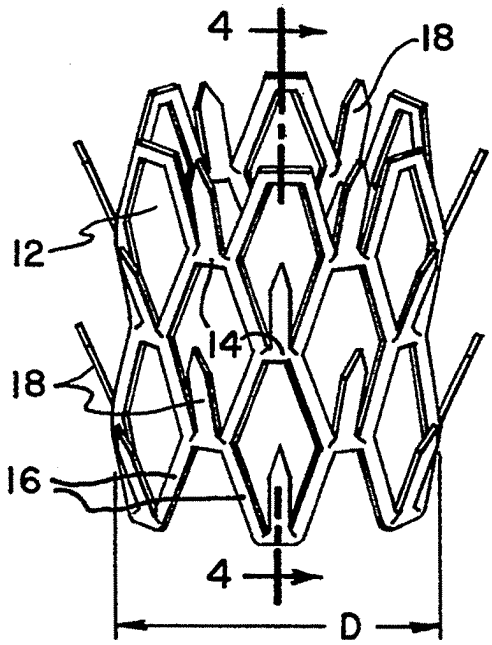


FIG. 1

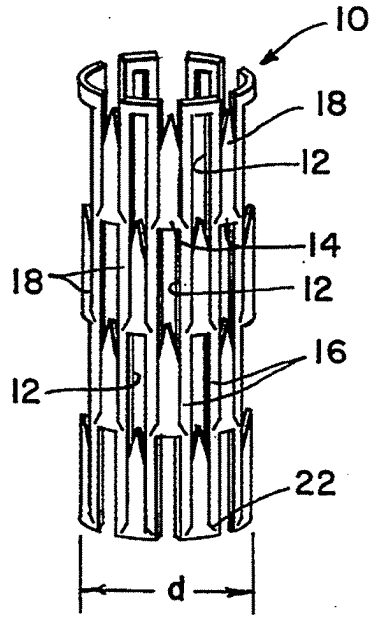


FIG. 2

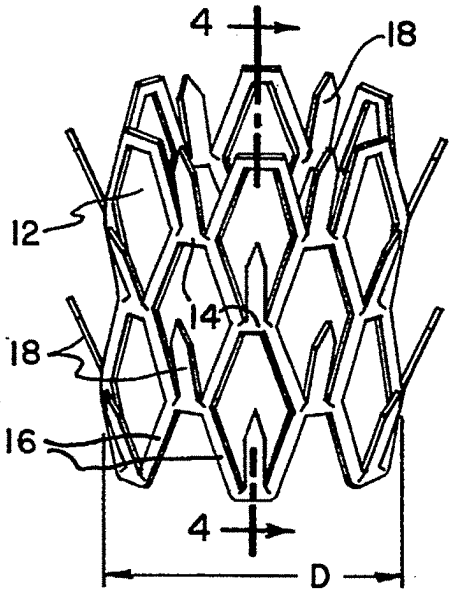


FIG. 3

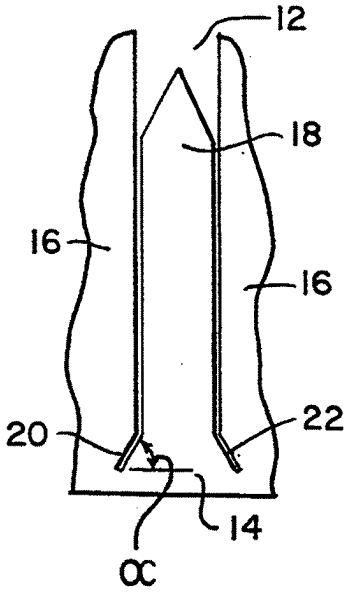


FIG. 4

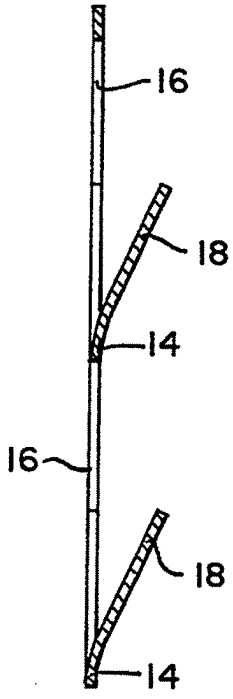
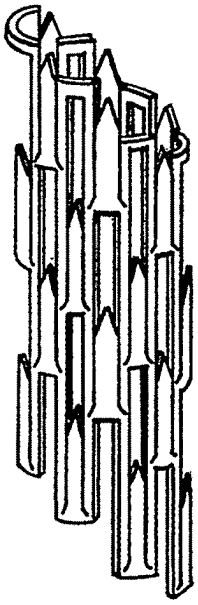


FIG. 5



INTRALUMINAL STENT

FIELD OF THE INVENTION

This invention relates to intraluminal stents and, more particularly, to intraluminal stents of the type used to retain a grafted stent within a blood vessel.

BACKGROUND OF THE INVENTION

Endoluminal grafts have been used to repair blood vessels affected with any of a variety of lesions which can compromise circulation through the blood vessel to a portion of the body. The graft may be made of dacron, expanded polytetrafluoroethelyne (ePTFE), or a natural substitute such as a vein or artery taken from another portion of the body. Typically, the graft is held in place within a blood vessel by means of an expandable stent.

A variety of different stents have been used and proposed for this purpose. One stent, known as a Palmaz stent, has been used as a means for anchoring a graft within a blood vessel. The Palmaz stent is illustrated in FIGS. 1A and 1B of Palmaz U.S. Pat. No. 5,102,417. In this patent, the Palmaz stent is characterized as an "expandable intraluminal graft" The patent contains an extensive description of the prior art and the problems which the Palmaz stent was designed to overcome. U.S. Pat. No. 5,102,417 (the "Palmaz patent") and its parents are hereby incorporated by reference into this specification.

The basic Palmaz stent comprises a mesh-like tubular member which can be expanded from a first diameter to a second diameter. The stent may be expanded by means of a balloon catheter, the force applied by the balloon exceeding the elastic limit of the stent so that when the balloon is deflated, the stent remains in its expanded form. Since expansion of the stent can be closely controlled, if the stent is expanded into contact with the surface of a blood vessel, a graft positioned between the stent and blood vessel can be secured within the blood vessel.

As explained in the Palmaz patent, the Palmaz stent provides benefits in addition to the ability to anchor a graft at a desired location within a blood vessel. For example, the stent can be used by itself to prevent the recurrence of stenoses, and to prevent recoil of an elastic vascular stenosis. It is usable in critical vessels such as the left main coronary artery where the possibility of the intimal flap blocking blood flow limits the use of balloon dilatation procedures.

SUMMARY OF THE INVENTION

The present invention provides an improvement over the basic Palmaz stent in that it provides a means for mechanically anchoring the stent to the blood vessel. In the preferred embodiment, these means comprise barbs which remain within the surface of the stent when the stent is in its unexpanded condition, but which extend from the surface of the stent when the stent is expanded. These barbs are adapted to engage the graft and the surface of the blood vessel to mechanically attach the stent to the vessel. Because friction is not solely relied upon to hold the stent in place, the stent may exert less force on the blood vessel which, in turn, means that a thinner stent requiring less force for expansion may be used. In addition, there may be less radial force permanently exerted in an artery after stent deployment which may be less injurious to the vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a preferred embodiment of the invention showing the stent in its unexpanded condition;

FIG. **2** is a perspective view of the stent of FIG. **1** in its expanded condition;

FIG. **3** is an exploded view of a portion of the stent showing the manner in which the barb is connected to the mesh-like wall of this stent;

FIG. **4** is a sectional view along the line **4**—**4** of FIG. **2**; and

FIG. **5** is a perspective view of a modification of the preferred embodiment showing the stent in its unexpanded condition with a staggered arrangement of circumferential ribs.

DETAILED DESCRIPTION OF THE INVENTION

In its preferred embodiment, the invention is intended to be used as part of a stented graft, but it is contemplated that the invention would have utility for other purposes, including but not limited to the purposes itemized in the Palmaz patent.

Delivery and deployment of a stent in accordance with the invention may be by conventional means including, but not limited to, the balloon catheters disclosed in the Palmaz patents. The mechanical delivery and deployment means disclosed in U.S. patent application Ser. No. 08/196,278 filed on Feb. 10, 1994, in the names of Michael and Ralph Marin and entitled APPARATUS AND METHOD FOR DEPLOYMENT OF RADIALLY EXPANDABLE STENTS BY A MECHANICAL LINKAGE may also be used. Since the device for delivering and deploying the stent forms no part of this invention, it is neither illustrated nor described in this application.

Referring now to the drawings, a stent comprises a tubular mesh-like member **10**. The stent may be made from a stainless steel tube or other metal in which elongated openings **12** are cut, for example by conventional laser cutting techniques or electrical discharge machining. Removal of the tubular material to form the elongated openings **12** results in a multiplicity of intersecting members which may be characterized as circumferential ribs **14** and bars **16** which are colinear with the axis of the tube. As shown in FIG. **1**, each of the circumferential ribs **14** intersects one of the colinear bars **16** at the halfway point of an adjacent rectangular opening **12**.

As explained in the Palmaz patents, the stent may be made of various materials, but a thin-walled stainless steel tube is preferred. The material must deform when pressure is applied to the interior surface of the tubular member (for example by means of a balloon) and, of course, must be strong enough to withstand any pressure applied by the blood vessel (or other body lumen) in which it is to be placed.

The diameter of the unexpanded stent is shown at "d" in FIG. **1**. When pressure is applied to the interior surface of the stent, the colinear bars **16** are deformed causing the openings **12** to assume a diamond-like shape. By virtue of this deformation of the bars **16**, the diameter of the stent increases from "d" to "D", with the length of the stent being reduced proportionately to accommodate the increase in diameter (compare FIG. **1** with FIG. **2**).

In accordance with the invention, a barb **18** extends into each of the elongated openings **12** from a circumferential rib **14** at one end of the opening. Each of the barbs lies flat in the surface of the tubular member in its unexpanded state. It has been discovered that if a pair of oblique slots **20** and **22** (see FIG. **3**) are provided in the circumferential rib **14** at its juncture with the barb **18**, when a force is applied to the inner surface of the stent, expansion of the stent will cause the barb **18** to move radially outwardly from the surface of the stent as it expands (see FIG. **4**). In other words, as the stent is deployed, the barbs **18** are also deployed so that when the stent contacts the surface of the blood vessel, the barbs penetrate the inner lining of the blood vessel to anchor the stent in place.

The dimensions of the components of the stent, including the barb are not critical and may be determined empirically. It is believed that the angle α illustrated in FIG. **3** should be between 30° and 60°, optimally 45°. Likewise the length of the slots **20** and **22** may be determined empirically with a view toward optimizing the deployment of the barbs without weakening excessively the circumferential ribs **14**. The slots **20** and **22** serve an important function in causing the barbs to deploy during expansion of the stent.

It is also possible that opposing barbs **18** may extend toward each other in each slot **12**. In other words, two barbs **18** would extend in opposite directions from each circumferential rib **14**. This, of course would double the number of barbs, which would enhance attachment of the stent to the blood vessel.

Also contemplated is a stent having a staggered arrangement of circumferential ribs **14** as shown in FIG. **5**. By staggering or displacing the circumferential ribs **14** as shown in FIG. **5**, expansion of the stent will create forces in an oblique direction which may increase the strain in the ribs **14** and thereby magnify the force on the junction between each barb **18** and rib **14**.

Many modifications of the illustrated embodiment are possible within the scope of the invention. The illustrated embodiment is therefore to be considered in all respects as illustrative and not restrictive; the scope of the invention being indicated by the appended claims, and not limited to the foregoing description.

What is claimed is:

1. An implantable intraluminal stent, comprising a tubular wall defined by a multiplicity of intersecting members forming a multiplicity of openings, said tubular wall being expandable from a first diameter to a second diameter upon application of a radially directed force to the interior surface of said wall, at least some of said intersecting members including a barb, each said barb lying flat in the surface of said tubular wall when it is unexpanded and extending out of the surface of said tubular wall for engagement of a lumen when it is expanded.

2. A stent according to claim **1**, wherein said barbs are colinear with the axis of said tubular wall.

3. A stent according to claim **2**, wherein said intersecting members include circumferential ribs, said barbs extending from said ribs.

4. A stent according to claim **1**, wherein oblique slots are formed in said ribs at each intersection of a barb and rib.

5. A stent according to claim **2**, wherein oblique slots are formed in said ribs at each intersection of a barb and rib.

6. A stent according to claim **3**, wherein oblique slots are formed in said ribs at each intersection of a barb and rib.

* * * * *

Declaration of Richard J. Saunders Regarding European Patent EP 1 066 804

I, Richard J. Saunders, affirm and declare as follows:

1. I was employed by Guidant Corporation from August of 1988 to September of 2004 as a principal engineer and later as Advisor, Laser Technology.

2. I am the named inventor of European Patent No. EP 0 714 641, directed to laser cutting of metal stents.

3. By March of 1996, the earliest filing date of Evysio's claimed priority applications, I was aware of others using lasers to cut stents.

4. Guidant began using lasers to cut stents from a tube of metal at least as early as November of 1994.

5. On November 21, 1995, Guidant employees visited Laser Pro Labs (LPL) in California. The visit is documented in an e-mail communication attached hereto as Exhibit A. LPL sold Lasag YAG Lasers to cut coronary stents. A letter from Lasag describing the YAG Laser and enclosing product literature is attached hereto as Exhibit B.

6. An LPL representative, Mr. George Shukov, disclosed that Johnson & Johnson, a major manufacturer of stents, had purchased five of the lasers by that time and was using them to manufacture stents.

7. LPL prepared a quote to sell a laser cutting system to Guidant, which is attached hereto as Exhibit C. As noted in the quote, the system was capable of cutting a 10mm stent, with .060 mm outer diameter and a 4 mill (0.004mm) wall thickness.

8. Therefore, prior to 1996, I was aware that at least LPL was using lasers to cut coronary stents from a tube.

I declare under penalty of perjury that the foregoing is true and correct.

Richard J. Saunders

In Santa Clara, California on January 28, 2006

Richard J. Saunders

EXHIBIT A.

Saunders, Richard (m) (SC)

From: Limon, Tim (SC)
To: Huss, Beverly (m) (SC); Cox, Daniel (SC); Callol, Joe (SC); Loeffler, Joe (SC); Ham, Kevin L (SC); Michaels, Marybeth (SC); Sirhan, Motasim (SC); Allen, Richard (SC); Chan, Randy (m) (SC); Eury, Robert (SC); Rapoza, Richard (SC); Renati, Richard (SC); Saunders, Richard (m) (SC); Owens, Tim (SC); Teaby, Greg (ACS)
Subject: Notes from Laser Pro Labs visit
Date: Wednesday, November 29, 1995 8:26AM

On Tuesday, November 21st, Motasim Sirhan and I visited with Laser Pro Labs (LPL) to keep our relationship with vendors active. We spoke with George Shukov. He shared information about his Model 104 Stent Cutting Laser. We covered several features of the system which are listed below:

Speed: Our most modern ACS laser (with circular interpolation) can cut a J&J pattern in about 9 minutes (roughly 50 per 8 hour shift) The Model 104 can cut 100 J&J stents per 8 hour shift (that's double the capacity)

Auto Feed: This eliminates the need for an operator to change individual stents. The model 104 has the ability to accept a single 36" tube, cut the stent, automatically advance the tube and cut the next stent. At the end of the run, the operator pulls out a drawer full of stents and loads the next 36" of tubing.

Auto Degate: George has developed a polishing process that alleviates the need for gates on the stents. This technology is included in the price of the laser. Stents can now be cut on the laser, be sonicated for 10 minutes, be polished and are now ready for inspection.

Beam Diameter: 0.0025"

Optical Delivery: A simple 90° bend from laser to stent.

Accuracy: The 104 has a low inertia Aerotech rotary encoder has the ability to make directional changes at 60 rpm without causing an error. Our current Anaround system has too much inertia and is under powered causing errors at high speeds. The overall positioning system has an accuracy of +/- 0.0002"

Reliability: LPL uses a Lasag YAG laser. Lasag is known as the industry leader in quality lasers for production environment. Also the Aerotech positioning system is on of the best. The 104 has positive air pressure applied to all of the encoder assemblies ensuring that particulates won't enter. The system is also vented removing particulates from the class 1 enclosure. George mentioned that he's only made 2 service calls in the last 6 months with 8 systems already in the field. J&J's stent reject rate is about 2%.

Direct Programming: The 104 has a PC based programming console running Windows 3.1. This alleviates the need for the serial links between PC's and Anorads. The console also has a video system that provides allows you to focus the beam without looking through a microscope. The console is lockable to ensure data / program security.

Price: $350K Including installation, training, technology transfer. J&J got a 5% discount when they ordered 5 lasers. We can negotiate.

Lead Time: 14-18 weeks. George has offered to sell us his 2nd laser (to be built) by early march.

EXHIBIT 8

LASAG
INDUSTRIAL·LASER

LASAG Corporation
Phone (708) 593-3021

702 West Algonquin Road

Arlington Heights, IL 60005-4416
FAX (708) 593-5062

December 1, 1995

Mr. Kevin Hann
Advanced Cardiovascular Systems
3200 Lakeside Drive
Santa Clara, CA 95052-8167
(408) 235-3936

Re: LASAG Lasers.

Dear Mr. Hann:

I enjoyed speaking with you regarding your laser stent cutting application. Enclosed please find a set of literature on our line of pulsed Nd-YAG lasers and beam delivery accessories.

LASAG is a Swiss manufacturer of precision laser sources and laser beam delivery systems for industrial products. At LASAG, we offer over 25 years of experience in the industrial laser market earning a position as the industry leader. Our organization is worldwide with thousands of lasers installed in facilities performing a wide range of applications that only our unique design would facilitate. We offer total manufacturing solutions by utilizing our vast applications experience to solve processing problems, offer a high quality, reliable product, and providing the continued support and training you require. We are committed to our customers and not only want to earn your business but strive to become your laser partner.

Please feel free to call with any questions that you may have. I look forward to hearing from you.

Sincerely,
LASAG CORPORATION

Fritz Muller
Vice President

ke
Encl

Compact Laser System KLS 126

A newly developed LASAG laser source of the well proven KLS series with the following features:

- *wide range of achievable parameters*
- *extensive monitoring possibilities*
- *easy operation*
- *smooth an effective integration possibilities into production systems*
- *complying with international safety regulations*
- *wide range of standard accessories*

Range of applications

The KLS 126 laser is a cutting and welding laser source, enabling cutting rates up to 1 m/min., welding depths up to 1 mm and spot diameters up to 1,2 mm. By using a laser beam deflection, or a fiber optic system, it is possible to extend and adapt the system for a range of applications.

Services

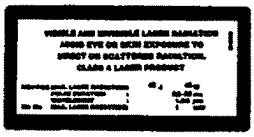
LASAG guarantees competent counselling on matters relating to applications, an intensive training of customers in operation and maintenance. LASAG's after sales service operates worldwide.

The Technology

The compact design of the laser head allows convenient mounting possibilities and easy maintenance.
The standard laser head is equipped with a monocular eyepiece and adjustable cross-hairs. As an option it can be replaced with a binocular or a viewing system with a closed circuit TV monitor.
A state-of-the-art laser control system incorporates three microprocessors for demanding real-time operations and allows a continuous adjustment of all important laser parameters, including the pulse energy. The input data is entered via the keyboard or the user interface. Ramping and burst parameters are also programmable. Full safety interlocks an comprehensive fault diagnostics are also provided within the control system. The operating panel is located on the power supply cabinet. As an option, it can be delivered mounted in a remote control cabinet with a connecting cable 5 m long.

Optional Fiber Optics

Instead of a standard laser head, it is possible to connect fiber optic modules for 1 to 6 fibers to the laser. This option extends the flexibility of the system and allows it to be used in particular together with production robots.



LASAG
INDUSTRIAL·LASERS

Specifications (nominal values)

Laser type Nd: YAG	KLS 126
Wave length	1,064 µm
Beam diameter	6 mm
Pulse duration	0,1–10 ms
Pulse frequency	300 Hz
Pulse power	4,5 kW
Pulse energy	30 J
Average power	120 W

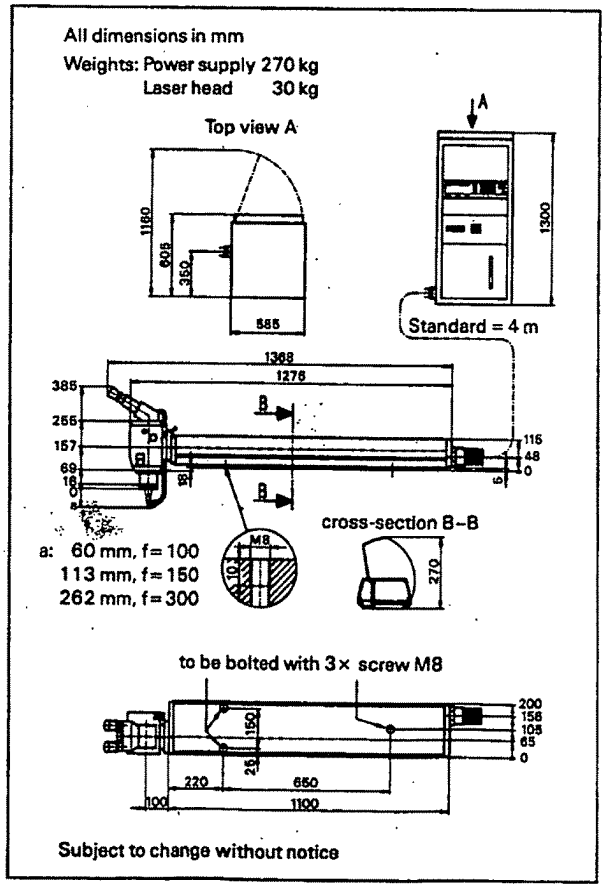
Services

Electrical	3×380 V/220 V ±10% (3 P+N+E)
Main frequency	50 Hz (60 Hz as option)
Power	11 kVA
Max. phase current (eff.)	16 A
Recommended fuses	20 A

Water cooling

Water inlet	2–10 bar, max. 18° C (64° F)
Water outlet	no backpressure
Water consumption (depends on load)	1–10 l/min.

Dimensions and weights



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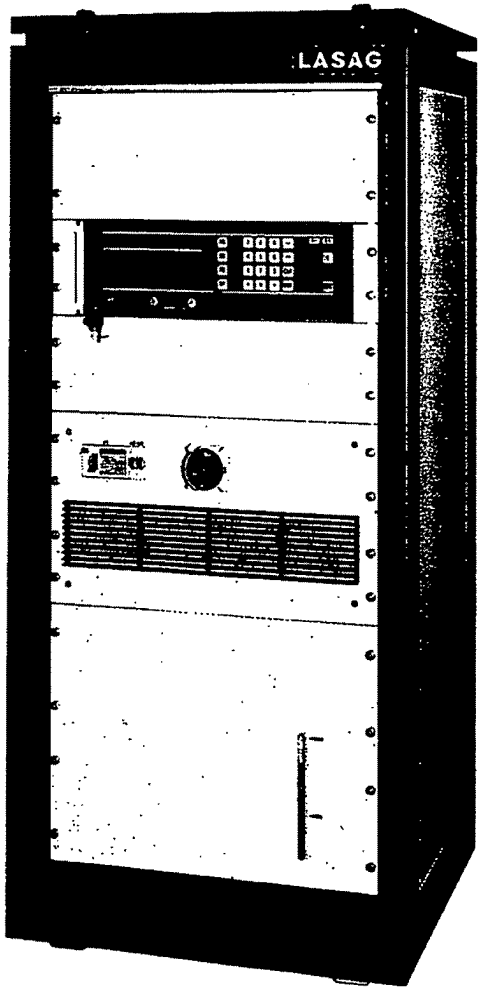
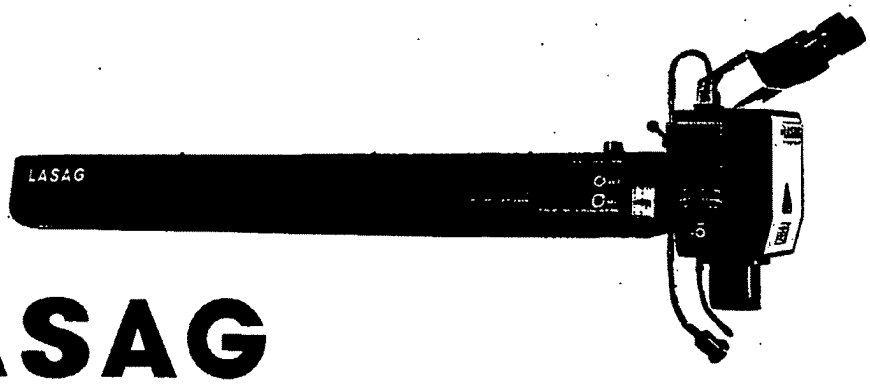
Lasag-Laser KLS 126





LASAG

INDUSTRIAL-LASERS

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(54) Expandable stent forming projecting barbs and method for deploying

(57) An intraluminal stent for implanting in a body lumen in which a plurality of connecting members are deformed radially outwardly to form projecting barbs for attaching the stent to a body lumen. The stent has a first, unexpanded low profile diameter for intraluminal delivery, and a second, larger expanded diameter for implanting in a body lumen in which projecting barbs are formed and which penetrate the body lumen to assist in attaching the stent to the walls of the body lumen.

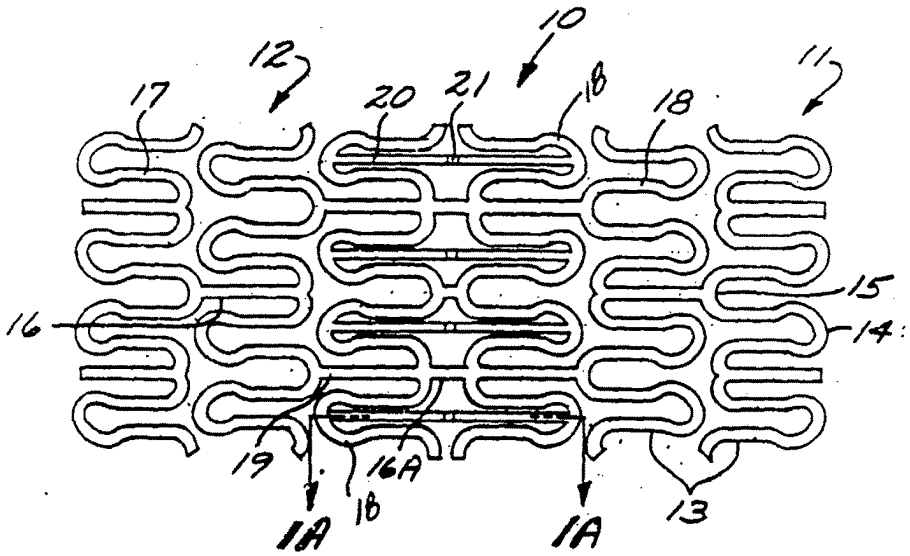


FIG. 1

EP 0 732 088 A2

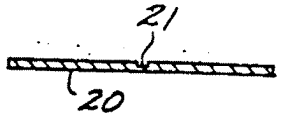


FIG. 1A

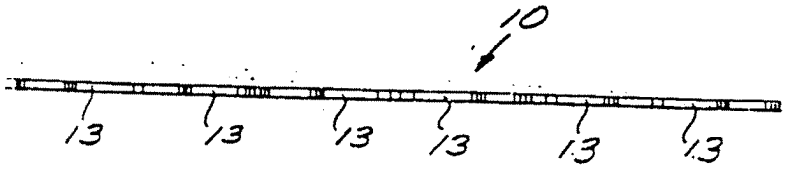


FIG. 1B

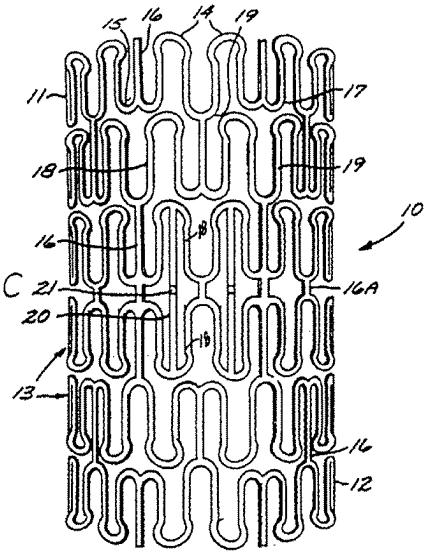


FIG. 1C

Description

The invention relates generally to endoprostheses and, more specifically, to an intraluminal stent for repairing a damaged or diseased artery, or to be used in conjunction with a tube graft for delivery to an area of a body lumen that has been weakened by damage or disease, such as an aneurysm of the abdominal aorta. Several areas of the body are particularly suitable for receiving an endoprosthesis, commonly referred to as an intraluminal stent, to hold open and insure the patency of a body lumen. Two such areas include the coronary arteries and the aorta, especially in the area where an aneurysm has developed.

An abdominal aortic aneurysm ("AAA") is an abnormal dilation of the arterial wall of the aorta in the region of the aorta that passes through the abdominal cavity. The condition most commonly results from atherosclerotic disease. Frequently, abdominal aortic aneurysms are dissecting aneurysms, that is aneurysms that are formed when there is a tear or fissure in the arterial lining or wall through which blood is forced and eventually clots, forming a thrombosis which swells and weakens the vessel. Abdominal aortic aneurysms do not cause pain, but are easily detected in a thorough physical examination. If the aneurysm is not detected and treated, it is likely to rupture and cause massive hemorrhaging fatal to the patient.

Treatment of AAAs comprises some form of arterial reconstructive surgery which commonly is referred to as a "triple-A" procedure. One such method is by-pass surgery, in which an incision is made into the abdominal cavity, the aorta is closed off above and below the site of the aneurysm, the aneurysm is resected, and a synthetic graft or tube sized to approximate the diameter of the normal aorta is sutured to the vessel to replace the aneurysm and to allow blood flow through the aorta to be reestablished. The graft commonly is fabricated of a biocompatible material that is compliant and thin-walled. Nylons and synthetic fibers such as those manufactured under the trademarks DACRON or TEFLON of the E.I. DuPont de Nemours, Co. have been found to be suitable for the construction of the graft. Studies have shown that the mortality rate associated with this surgical procedure is favorable (less than 5%) when it is performed prior to rupture of an aneurysm. However, patients having an AAA typically are over 65 years of age, and often have other chronic illnesses which increase the risk of perioperative or post-operative complications. Those patients thus are not ideal candidates for this type of major surgery. Further, it has been pointed out that this procedure is not often successfully resorted to after an aneurysm has ruptured (the mortality rate increases to over 65%) because of the extensiveness of the surgery and the time required to prepare a patient for it.

Because of the aforementioned disadvantages to conventional surgical methods, another procedure was developed as an alternative to conventional, major surgery. This method also involves emplacement of a graft at the site of the aneurysm; however, the graft is deployed there by being routed through the vascular system carried by a catheter, wire or other device suitable for negotiating the vasculature. The graft and its deployment system often are introduced into the blood stream percutaneously with a femoral approach and the entire procedure can be performed using local rather than general anesthesia.

Once the graft has been positioned at the aneurysm, it is disengaged from the delivery system and can be affixed to the aortic wall both distally and proximally of the aneurysm. For this purpose, grafting systems usually include fixation means such as staples or hooks which can be manipulated and driven into the intima of the vessel via some mechanical feature of the system, or by some physical process, such as expansion of the graft through application of pressure. To avoid premature detachment of the graft and to prevent the attachment elements from damaging the vessels or halting the forward movement of the system while the graft is being routed to the treatment site, the systems often are provided with a feature such as a capsule or a sheath that protects and contains the graft until such time as deployment is desired.

Once the graft is in place, it is positioned in the vessel spanning the site of the aneurysm such that the walls of the graft are generally parallel to the walls of the affected area of the aorta. The aneurysm thus is excluded from the circulatory system by the graft rather than being resected altogether. If the aneurysm is a dissecting type and a thrombosis exists between the walls of the aorta, the now-excluded aneurysm beneficially may provide structural support for the graft.

Grafting systems are known that include what commonly is referred to as an attachment system for deploying the graft. The attachment system is a tubular device which is fitted inside and is generally coaxial with the graft, and which can extend out of the graft at either or both the proximal and distal ends thereof. The attachment system often has a lattice-like or open weave structure, which provides it with flexibility and which promotes rapid endothelial tissue growth through the structure once the graft has been deployed. It may be provided with additional hook-like elements for penetration of the intimal walls for attachment of the graft to the aorta, or those hook-like elements may be provided on the graft itself. Graft systems of type described can be found in U.S. Patent Nos. 4,787,899 (Lazarus) ; 5,104,399 (Lazarus) ; 5,219,355 (Parodi et al.); and 5,275,622 (Lazarus). A stent and graft combination can be found in U. S. Serial No. 340,112, filed November 15, 1994, which is commonly assigned to the same assignee as the present invention, namely Advanced Cardiovascular Systems, Inc., Santa Clara, California. Generally, prior art systems that employ attachment means which include hooks or staples create a very large profile for delivery through a body lumen.

The actual function of delivering the graft may be accomplished by inflating a balloon of a catheter by introducing pressurized fluid into a lumen of the catheter from a source external to the patient. Inflation of the balloon applies a force to the graft, and to any attachment system supplied therein, which force extends radially and presses the graft and attachment system into the vessel wall just above and just below the aneurysm. Other devices used to attach a graft to the aortic wall for AAA repair include intravascular stents of the type found in U.S. Patent No. 5,316,023.

In order for a stent to be used most advantageously with a graft deployment system for treatment and repair of aneurysms, the stent must be composed of a biocompatible material and simultaneously must be flexible enough to comply with the catheter or other element used to route the graft through the often tortuous vascular path to the site of the aneurysm and strong enough radially to maintain the opening in the graft once delivered. It is important that the stent or stent-and-graft combination have a low profile for intraluminal delivery. The stent must be well suited to deployment by a delivery system that is not overly complex and, thus, is reliable and easy to operate. Further, it is desirable that the stent be expandable, so that upon application of a force or physical change from within sufficient to cause radial expansion, it encourages affixation of itself and the graft to the aortic walls. Although various stents have been proposed, none adequately provides all of these desirable features.

Another area in which stents commonly have been used are the coronary arteries, for the purpose of repairing a damaged or diseased vessel. In typical prior art situations, the stent is mounted on the balloon portion of a catheter and is delivered intraluminally by known methods to a specific location in a coronary artery. Generally, a stent is deployed after a patient has undergone a PTCA (percutaneous transluminal coronary angioplasty) procedure in which a lesion or other obstruction in the artery has been dilated by known methods. Deploying an intravascular stent at the site where an angioplasty has occurred will reduce the likelihood of a restenosis and can assist in tacking up any dissections and, in general, reinforce the vessel wall.

Most, but not all, stents currently described in the art provide a smooth outer wall surface which, when expanded, does not penetrate into the vessel wall. Thus, some prior art stents do not provide adequate fixation methods to attach the stent to the vessel wall during deployment.

What has been needed and heretofore unavailable is a stent for use in combination with a graft which has a high degree of flexibility for efficient advancement through tortuous passageways, which can be radially expanded from a relatively small diameter and low profile to a relatively large diameter without substantial longitudinal contraction, and which exhibits mechanical strength sufficient to penetrate the vessel walls thereby resisting migration and to maintain the patency of a synthetic graft implanted at the site of an aneurysm.

SUMMARY OF THE INVENTION

Embodiments of the present invention are directed to an intravascular stent which can be used in combination with an aortic graft to repair an abdominal aneurysm, or separately to reinforce a coronary artery after a PTCA procedure. As used herein, reference to the "proximal" is toward the outside of the patient and away from the stent while reference to the "distal" is toward the stent, which generally is mounted on the balloon portion of a catheter. The proximal and distal definitions apply equally to directions in other parts of the vascular system and especially to the aorta and coronary arteries.

In a preferred embodiment, the stent is attached to the distal end of a tubular graft such that at least a portion of the stent is exposed distally, beyond the distal end of the graft. Thereafter, the graft-and-stent combination is deployed intraluminally such that the stent and the distal end of the graft are positioned distally of the aneurysm, while the proximal end of the graft extends proximally of the aneurysm. Thus, the tubular graft will span the diseased area of the aneurysm.

The intravascular stent is comprised of a plurality of cylindrical elements that are interconnected to each other by a plurality of connecting members. The cylindrical elements on a first stent section face one direction and in a second stent section the cylindrical elements face the opposite direction. At least some of the connecting members between the first and second stent sections have a notch to create a weakened area which will permit the connecting member to deform or buckle outwardly when the stent is expanded. More than one notch can be formed in the connecting members. When the stent is expanded from a low profile, first diameter, the connecting members having a notch will buckle outwardly, forming a projecting barb which will penetrate the aortic wall and thereby attach the stent-and-graft combination to the aortic wall. Because the first and second stent sections have oppositely-facing cylindrical elements, during expansion a compression force is created which causes the connecting members to buckle at the notched area. Several of these projecting barbs may be employed to affix the stent-and-graft combination. It also is possible to attach a stent to the proximal end of the tubular graft to affix the proximal portion of the tubular graft to the aortic wall. Further, it is envisioned that the stent can be employed with a bifurcated graft (not shown) which generally is used when the aortic aneurysm is close to the aortic bifurcation.

In another embodiment of the invention, the connector members having a notch are offset or angulated from the longitudinal axis of the stent. When the stent is rotated or twisted, the connecting members are compressed, forcing the members to align and buckle out-

wardly to provide projecting barbs as described above. Rotating the stent can be accomplished in numerous ways, including holding one end stationary while rotating the other end, or counter-rotating each of the ends respective to each other. This rotational or twisting action will cause the connecting members having a notch to buckle outwardly as long as the overall length of the stent does not appreciably increase. This embodiment can be used, as described above, with a stent-and-graft combination for repairing aortic aneurysms.

A further embodiment of the invention includes an intravascular stent having a first stent section and a second stent section, each section having a plurality of oppositely-facing cylindrical elements connected by a plurality of connecting members. Some of the connecting members have one or more notches which provide a weakened area in the connector member. When the ends of the stent are moved toward each other, this causes the weakened area or notch in the connecting members to deform so that the connecting member buckles outwardly to form a projecting barb. This embodiment of the stent also can be used with a stent-and-graft combination to repair an aortic aneurysm.

It also is contemplated that each of the embodiments can be used to repair other body lumens, such as the coronary arteries. Thus, for example, the stent of the present invention can be implanted in a coronary artery after a PTCA procedure in order to repair a damaged or diseased portion of the artery. The stent will be deployed and implanted similar to that described above, with the exception that the projecting barbs will be correspondingly smaller in the coronary arteries than in the aorta. The projecting barbs will assist in firmly attached the stent to the vessel wall so that it is more securely attached to the vessel wall once it has been implanted. A clear advantage of the stent for use in the coronary arteries is its low delivery profile and its positive attachment features upon implanting.

In another embodiment of the invention, the notched connecting member has a bevelled-edge member affixed to at least a portion of the connecting member by any known means, such as by welding. The bevelled-edge member has a point that extends outwardly from the outward-most portion of the projecting barb so that the bevelled-edge member and the projecting barb penetrate the vessel wall.

Other features and advantages of the present invention will become more apparent from the following detailed description taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a plan view depicting a stent embodying the present invention having a plurality of connecting members which will become projecting barbs upon expansion.

FIG. 1A is a cross-sectional view taken along lines 1A-1A depicting a connecting member having a weakened area or notch.

FIG. 1B is an elevational view of the stent of FIG. 1 where the notched connecting members have not been deformed.

FIG. 1C is a perspective-elevational view of the stent of FIG. 1 rolled into a cylindrical configuration, but not expanded (the backside of the cylinder is not shown for clarity purposes).

FIG. 2 is a plan view depicting the stent of FIG. 1 in which the stent has been expanded.

FIG. 2A is cross-sectional view taken along lines 2A-2A depicting the notched connecting member in its deformed configuration as a projecting barb.

FIG. 2B is an elevational view of the expanded stent of FIG. 1 depicting the notched connecting member projecting outwardly as a projecting barb.

FIG. 2C is a partial elevational view of the stent of FIG. 2 rolled into a cylindrical configuration and depicting the projecting barbs as they appear projecting outwardly when the stent is expanded.

FIG. 2D is a plan view depicting the stent of FIG. 1 in which the notched connecting members each have more than one notched or weakened portion to facilitate deformation of the connecting member.

FIG. 2E is a partial plan view of one of the notched connecting members having a bevelled-edge member affixed to a portion of the connecting member, the view being depicted in an unexpanded configuration.

FIG. 2F is a plan view of the connecting member of FIG. 2E in which the stent has been expanded causing the connecting member to compress and to project outwardly so that the projecting barb and the bevelled-edge member project outwardly.

FIG. 2G is a side view of the connecting member of FIG. 2F depicting the connecting member buckled outwardly and forming a projecting barb and depicting the bevelled-edge member projecting outwardly for deeper penetration into the vessel wall.

FIG. 3 is a plan view depicting another embodiment of the stent having connector members angulated or offset from the longitudinal axis of the stent.

FIG. 3A is an elevational view of the stent of FIG. 3 depicting the stent in its flat and unexpanded configuration.

FIG. 4 is a plan view of the stent of FIG. 3 in an unexpanded configuration but with the two stent sections aligned such that the connector members having a notch have been twisted to project outwardly as projecting barbs.

FIG. 4A is a plan view of the stent of FIG. 4 in which the connector members having a notch are projecting outwardly to provide projecting barbs.

FIG. 5 is a plan view depicting another embodiment of the stent in which connector members having a notch separate two sections of the cylindrical elements.

FIG. 5A is an elevational view of the stent of FIG. 5 in an unexpanded state and with the connector ele-

ments undeformed.

FIG. 6 is a plan view of the stent of FIG. 5 in which the two sections of cylindrical elements have been forced toward each other thereby deforming the connector members with a notch into providing projecting barbs.

FIG. 6A is an elevational view of the stent of FIG. 6, in its unexpanded state, depicting the connector members having a notch deformed to provide projecting barbs.

FIG. 6B is an elevational view of the stent of FIG. 6 in its rolled-up configuration before the stent ends are forced together to form projecting barbs.

FIG. 7 is a partial cross-sectional view of a stent embodying the present invention attached to a tube graft and being implanted in a AAA procedure.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Embodiments of the invention relate to an intravascular stent, one or more of which is used in conjunction with a known tubular graft or bifurcated graft for repairing body lumens of all types. As described herein, reference is made to repairing an aortic aneurysm, coronary arteries, and other vessels, however, other body lumens are equally suited to receive the stent of the present invention.

In keeping with this, FIGS. 1-2D depict an intravascular stent 10 having a first stent section 11 and a second stent section 12. In the embodiment shown, each of first stent section 11 and second stent section 12 have a plurality of cylindrical elements 13 which are connected by a plurality of connecting members 16. Each of cylindrical elements 13 are comprised of a series of peaks 14 and valleys 15 in a serpentine manner. As depicted in FIGS. 1-1B, stent 10 is in a flattened condition and can be formed from a flat sheet of material as will be described herein. Stent 10 also can be formed from a piece of tubing using known chemical etching or laser cutting techniques.

Due to the serpentine nature of cylindrical elements 13, in addition to the connecting members 16, there appears a pattern of W-members 17, U-members 18, and Y-members 19. As can be seen, the radii in the various W-, U- and Y-members are different to accommodate differing expansion rates of the various members and to provide more uniform expansion, as will be described herein.

In a preferred embodiment, first section 11 and second section 12 are connected by a plurality of notched connecting members 20 which are designed to buckle or deform during expansion of stent 10. To accomplish the proper deformation of notched connecting member 20, a notch 21 is cut into notch connecting member 20 to provide a weakened area and to allow deformation to take place at that point. As can be seen in FIG. 1A, notch 21 is cut a distance into notched connecting member 20, but not all the way through. It is intended that notched connecting member 20 deform and buckle during expansion, but not to break apart at notch 21 Thus, notch 21 is to be cut into connecting member 20 a distance sufficient to cause a weakened area, but not so deep as to cause failure and breaking of notched connecting member 20 at the notched area. Notched connecting member 20 also can have several more notches so that connecting member 20 can buckle more easily. Thus, end notches near the ends of connecting member 20 will enable the connecting member to buckle more easily and thereby form projecting barb 22.

Turning to FIG. 1C, the flat sheet of stent 10 as depicted in FIG. 1 has been rolled into a cylindrical configuration with the back side of the stent not shown for purposes of clarity. Also, only two notched connecting members 20 are depicted, however, any number of notched connecting members 20 can be provided to accomplish the intended use. Stent 10 of FIG. 1C is in a non-expanded configuration. When the stent 10 is manufactured from a flat sheet of material as depicted in FIG. 1, it must be rolled into the cylindrical configuration depicted in FIG. 1C and the longitudinal ends of the stent must be welded, brazed, soldered or joined together by any known means. The stent of FIG. 1C also can be formed from a single piece of tubing thus eliminating the steps of rolling it into a cylindrical configuration and affixing the longitudinal ends.

FIGS. 2-2B depict stent 10 as it is formed from a flat sheet of material and in its expanded configuration. These drawing figures provide a clear picture of the expansion properties of stent 10 and its impact on notched connecting member 20, but in use stent 10 would not be expanded in its flattened configuration. As shown in FIG. 2, when stent 10 is expanded, the W-, U- and Y-members are deformed, however, the distance between the members remain substantially the same, because connecting members 16, which separate each of cylindrical elements 13, do not change in length. Importantly, the length of notched connecting member 20 changes in response to the bending and expansion of U-members when stent 10 is expanded outwardly. As expansion occurs, connecting members 16, which connect first stent section 11 to second stent section 12, are in tension but they cannot stretch. This tension creates an opposite compressive force on connecting member 20 which buckles at notch 21 and shortens in length, thereby forming projecting barb 22. When the expansion occurs, the weakened area of notch 21 allows notched connecting member 20 to deform thereby forming projecting barb 22 as depicted in FIGS. 2A and 2B. None, the connecting members 16 which do not have notches deform or buckle, but rather each un-notched connecting member remains the same length, thereby providing an expanded stent that does not appreciably shorten during expansion.

The stent shown in FIG. 2C is the stent of FIG. 2 rolled into a cylindrical configuration and expanded. On-

ly one cylindrical element of first stent section 11 is depicted and it is shown connected to second stent section 12. As can be clearly seen, notched connecting member 20 has deformed radially outwardly resulting in projecting barb 22. It is intended that projecting barbs 22 contact and penetrate the vessel wall to assist in affixing stent 10 during the deployment and implanting procedure, as will be further described.

It is important to note that with the present embodiment, the unexpanded stent 10 of FIG. 1C has an extremely low profile which allows the stent to be deployed through the vascular system with relative ease. Only after the stent has been positioned at the site at which it will be implanted, is it expanded. The projecting barbs 22 form during radial expansion. Thus, the present embodiment provides a clear advantage over prior art devices where the delivery profile is substantially higher because attachment hooks or other attachment devices increased the profile during delivery rather than projecting outwardly only upon expansion, as occurs with the present embodiment.

In FIG. 2D, the stent of FIG. 1 is depicted with more than one notch 21 in each connecting member 20 to facilitate deformation into projecting barbs 22. The notches 21 will provide weakened areas in connecting members 20. When the stent is expanded from its first, low profile diameter, the weakened areas around notches 21 allow connecting members 20 to buckle and deform outwardly to form projecting barbs 22.

In the event it is desirable to increase the depth to which projecting barbs 22 penetrate into the vessel wall, a bevelled-edge member 25 can be attached to connecting members 20. As can be seen in FIGS. 2E-2G, bevelled-edge member 25 is attached to connecting member 20 at point 26 by any known method, such as by welding, soldering or brazing. As described above, when the stent is expanded, the distance from one end of the connecting member 20 to the other end becomes shorter and causes connecting member 20 to buckle or deform outwardly, thereby forming projecting barbs 22. As can be seen more clearly in FIG. 2G, when projecting barb 22 projects outwardly, bevelled-edge member 25 projects even further outwardly, providing a barb that will penetrate even deeper into a vessel wall.

One important feature of the present embodiment is that first stent section 11 and second stent section 12 are aligned so that the "U"-shaped members 18 oppose one another. The peaks of the U's are attached by short connecting members 16A, while the base of the U's are connected by the longer, notched connecting members 20 that have been weakened (by notches or by other means as described herein). When the stent is expanded from its low-profile first diameter to its expanded second diameter, short connecting members 16A are placed in tension against the longer connecting members 20 which are in compression. In order for the cylindrical elements 13 connected by long connecting members 20 and short connecting members 16A to expand, one of the two connecting members must fail. Because the compression-loaded, longer connecting members 20 are inherently weaker than the tension-loaded short connecting members 16A, the longer connecting members 20 will fail. Since the long connecting members 20 are selectively weakened, such as by notch 21, the members 20 will selectively, and by design, fail outwardly to create projecting barbs 22.

In another embodiment of the invention, as depicted in FIGS. 3-4A, stent 10 has substantially the same overall configuration as that shown in FIG. 1, with the exception of the location of notched connecting members 20. As can be seen in FIG. 3, stent 10 is in a flattened condition and first stent section 11 is offset from second stent section 12, and each section is joined to the other by notched connecting members 20. Unlike the stent of FIG. 1, which required radial expansion to deform notched connecting members 20, the stent of FIG. 3 must be twisted to deform notched connecting members 20.

As seen in FIGS. 4 and 4A, unexpanded stent 10 now has notched connecting members 20 in alignment with the longitudinal axis of the stent and first stent section 11 is axially aligned with second stent section 12. By moving first stent section 11 in axial alignment with second stent section 12, notched connecting members 20 will deform at notch 21 resulting in projecting barb 22. To insure that projecting barb 22 forms radially outwardly, during the twisting motion first stent section 11 and second stent section 12 must be constrained so that they do not lengthen and change the overall length of stent 10. As can be seen in FIG. 4B, stent 10 has been rolled into its cylindrical configuration with notched connecting members 20 angulated so that they are not axially aligned with the longitudinal axis of stent 10. Once first stent section 11 is rotated or twisted with respect to second stent section 12, it will bring notched connecting members 20 into axial alignment with the longitudinal axis of stent 10 and the weakened area of notch 21 will permit notched connecting members 20 to deform outwardly, thereby forming projecting barb 22.

In another embodiment of the invention as depicted in FIGS. 5-6B, stent 10 is comprised of a first stent section 11 and second stent section 12, each having a plurality of cylindrical elements 13. First stent section 11 is spaced apart from second stent section by notched connecting members 20 each having a notch 21 to form a weakened area. As with the other stent configurations, the cylindrical elements 13 are connected by connecting members 16. As can be seen more clearly in FIG. 6A, projecting barb 22 is formed when first stent section 11 and second stent section 12 are forced closer together, thereby causing notched connecting members 20 to deform outwardly and thereby form projecting barb 22. Thereafter, the stent can be expanded so that it expands from a first, low profile diameter to a second larger diameter to contact the vessel wall. As with all of the embodiments of the present invention, the first, unexpand-

ed diameter of the stent provides a very low profile for delivery purposes through the body lumen of a patient.

With respect to each of the embodiments shown in FIGS. 1-6C, each stent embodiment can be delivered intraluminally in much the same manner. Stent 10 can be mounted on the balloon portion of a delivery catheter and delivered intraluminally in a portion of a body lumen. Once stent 10 is positioned at the site where it is to be implanted, the balloon portion of the catheter is expanded by known means to expand the stent outwardly into contact with the body lumen. An example of one method of deploying stent 10 is depicted in FIG. 7. The balloon portion of a delivery catheter can be substituted for by any expansion member capable of receiving stent 10 and expanding or urging the stent outwardly into contact with a body lumen. Thus, other means are available to urge outwardly and expand stent 10 such as mechanical, hydraulic, pneumatic, and by phase transition using memory-shaped alloys or superelastic alloys.

As is shown in FIG. 7, a stent 10 has been attached to an aortic tube graft 35 at both the distal end and proximal end of the tube graft. While a stent 10 is affixed to each end of tube graft 35, it is possible to attach a stent only to the distal end of tube graft 35, leaving the proximal end free. Due to the high pressure of blood flow in the aorta, the proximal end of tube graft 35 does not necessarily have to be firmly attached to the aortic wall 36. In FIG. 7, the stent and tube graft combination is mounted on balloon 40 and is delivered intraluminally by over-the-wire catheter 50. Generally, guidewire 60 having distal tip 70 is used to navigate the vasculature of the patient and to assist in positioning the catheter and balloon carrying the stent-and-tube graft combination. It is important to position the tube graft 35 so that it spans aneurysm 37 and completely diverts blood flow from the aorta through the tube graft, so that no blood flow leaks around the distal or proximal end of the tube graft and into aneurysm 37. Importantly, stent 10 should be expanded into the aortic wall 36 only where there is healthy tissue, and not where the aneurysm 37 has weakened the vessel wall.

Although a particular form of catheter has been described to route the graft-and-stent combination to the aneurysm, it will be apparent to those skilled in the art in treating aneurysms and similar conditions and of PTCA catheter design, that catheters having various configurations could be used successfully to perform the same functions. For example, well-known fixed wire and rapid exchange wire systems also can be used in the delivery system described above.

With further reference to FIG. 7, stent 10 is shown in its expanded configuration with projecting barbs 22 projecting outwardly and penetrating aortic wall 36. With projecting barbs 22 penetrating aortic wall 36, stent 10 is firmly implanted and attached to aortic wall 36 so that there is no possibility of the stent migrating once it is implanted. As shown in FIG. 7, the stent of FIG. 1C is used to anchor tube graft 35 to the aortic wall. Thus, balloons 40 are used to expand stent 10 radially outwardly, thereby causing the notched connecting members 20 to deform and project outwardly forming projecting barbs 22. Importantly, the overall length of stent 10 does not appreciably change when it is expanded, because connecting members 16A do not change in length and first stent section 11 and second stent section 12 are constrained from moving toward each other during expansion.

The expansion properties of stainless steel make it a preferred material for stent 10. Other materials are contemplated, which include combinations of stainless steel and polymer materials. Further, other materials might be used including tungsten, platinum, gold or combinations of these materials in forming stent 10. Stent 10 can be formed from a flat sheet of material or from a single sheet of stainless steel tubing, by chemically etching, laser cutting, or by using electronic discharge machining. A presently preferred mode of making stent 10 is found in co-pending application U.S. Serial No. 08/345,501, entitled Method and Apparatus for Laser Cutting Small Objects, which is commonly assigned to Advanced Cardiovascular Systems, Inc. of Santa Clara, California. Other details of the various processes by which a stainless steel stent 10 can be manufactured can be found in co-pending U.S. Serial Nos. 08/175,214 and 08/164,986. Further details of chemically etching stent 10 can be found in U.S. Serial No. 08/340,112, entitled Intraluminal Stent for Attaching a Graft, also commonly assigned to Advanced Cardiovascular Systems, Inc., Santa Clara, California.

It also is contemplated that the weakened portion of connecting member 20 result might be made to from something other than notch 21. In other words, it is intended that the invention not be limited to a weakened portion in the form of notch 21. Thus, the weakened portion of connecting member 20 can include an area along connecting member 20 that is thinner or necked-down relative to the rest of the member. The weakened portion also can be formed by a metal different from the metal forming the rest of the stent, or by selectively treating an area of the primary stent material. For example, the first and second stent sections 11,12 can be formed from stainless steel, while a portion of connecting member 20 can be formed from any material having a lower modulus of elasticity which material will deform and bend more easily than the stainless steel.

While the invention has been illustrated and described herein in terms of its use as an endoprosthesis -- for implanting in a body lumen such as a coronary artery or to be attached to a tubular graft or bifurcated graft for use in the aorta to repair an aortic aneurysm -- it will be apparent to those skilled in the art that the stent can be used in other instances in other vessels of the body. Because the described stent has the feature of forming a positive attachment barb after the stent has been routed through the vasculature of a patient to a specific site, and because it has a low profile during delivery, the stent

is particularly well suited for implantation in almost any vessel where such devices can be used. These features, coupled with the fact that the stent does not retract or recoil to any great degree after it is radially expanded, provides a highly desirable support member for other types of endoprostheses.

Other modifications and improvements may be made without departing from the scope of the invention. For example, the various drawing figures depict several configurations of the stent and various sizes, each of which can be modified to suit a particular application without departing from the scope of the invention.

Claims

1. An expandable intraluminal stent (10) for implanting in a body lumen, comprising:

   a first stent section (11) having at least one cylindrical element (13) facing a first direction;
   a second stent section (12) having at least one cylindrical element (13) facing a second direction opposite to said first direction;
   a plurality of connecting members (20) connecting said first section to said second section; and
   a weakened portion (21) in at least some of said connecting members, said connecting members being deformable at said weakened portion to provide a plurality of projecting barbs (22).

2. The intravascular stent of claim 1, wherein said weakened portion (21) includes at least one notch in said connecting members (20).

3. The intravascular stent of claim 1, wherein said connecting members (20) have a bevelled- edge member (25) attached to a portion thereof, said bevelled-edge member penetrating the body lumen when said connecting members (20) are deformed outwardly.

4. The intravascular stent of claim 1, wherein the overall length of said stent in its unexpanded and expanded configurations is substantially the same.

5. An intraluminal stent (10) for implanting in a body lumen, comprising:

   a first stent section (11) and a second stent section 12) each having at least one expandable cylindrical element (13) which are interconnected so as to be aligned on a common longitudinal axis;
   a plurality of connecting members (20) connecting said first stent section to said second stent section; and
   a notch (21) in at least some of said connecting members (20) providing a weakened area so that said connecting members having a notch can be deformed outwardly to form a plurality of projecting barbs (22) for penetrating the body lumen.

6. The intravascular stent of claim 1 or clam 5, wherein said stent has a smooth outer surface having no projections or rough edges and a first, unexpanded diameter providing a low profile for intraluminal delivery.

7. The intravascular stent of claim 1 or claim 5, wherein said stent has a second, expanded diameter so that said outer surface of said stent contacts the body lumen and said plurality of projecting barbs contact the body lumen.

8. The intravascular stent of claim 7, wherein said plurality of projecting barbs (22) penetrate the body lumen.

9. The intravascular stent claim 1 or claim 5, wherein said stent is attached to a tubular graft (35).

10. The intravascular stent of claim 1 or claim 5, wherein said stent is formed from a single piece of tubing.

11. The intravascular stent of claim 1 or claim 5, wherein said stent is formed from a flat sheet of material.

12. The intravascular stent of claim 11, wherein said flat sheet of material has a first longitudinal edge and a second longitudinal edge, and said stent is rolled into a cylindrical configuration from said flat sheet of material so that said first longitudinal edge abuts said second longitudinal edge and is attached thereto.

13. The intravascular stent of claim 5, wherein said first stent section and said second stent section are expanded from within causing said connecting members having a notch to deform outwardly.

14. The intravascular stent of claim 5, wherein said first stent section is twisted relative to said second stent section in order to deform said connecting members having a notch thereby forming said projecting barbs.

15. The intravascular stent of claim 5, wherein said first stent section and said second stent section are forced toward each other thereby deforming radially outwardly said connecting members having a notch and forming said projecting barbs.

16. The intravascular stent of claim 5, wherein at least some of said connecting members have a plurality of notches.

17. The intravascular stent of claim 5, wherein said connecting members having a notch have a bevelled-edge member (25) attached to a portion thereof, said bevelled-edge member penetrating the body lumen when the stent is expanded.

18. A method for implanting an intraluminal stent (10) in a body lumen where said stent has a plurality of cylindrical elements (13) which are expandable in a radial direction and which are interconnected so as to be aligned on a common longitudinal axis, and said stent having a plurality of connecting members (20) for interconnecting said cylindrical elements, where at least some of said connecting members have a notch so that as said cylindrical elements (13) are radially expanded said connecting members (20) having a notch buckle outwardly to form a plurality of projecting barbs (22), the method comprising:

providing a delivery catheter (50) having an expansion member (40) at its distal end;
mounting said intraluminal stent on said expansion member of said catheter;
delivering said stent on said expansion member of said catheter percutaneously through the patient's vasculature to a specific location;
expanding said expansion member and thereby expanding said stent outwardly into contact with the body lumen;
forming a plurality of projecting barbs (22) by deforming the connecting members (20) having a notch (21) so that they buckle outwardly, said projecting barbs penetrating the body lumen; and
contracting said expansion member and withdrawing said catheter and said expansion member from the patient leaving said stent implanted in the body lumen.

19. The method of implanting an intraluminal stent of claim 18, wherein said stent is attached to a tubular graft (35) prior to said mounting step so that said stent and tube graft combination can be used for repairing an aortic aneurysm.

20. The method of implanting an intraluminal stent of claim 19, wherein said connecting members having a notch (21) also have a bevelled-edge member (25) attached to a portion thereof, the method further comprising penetrating the body lumen by said bevelled-edge member when the connecting members having a notch buckle outwardly.

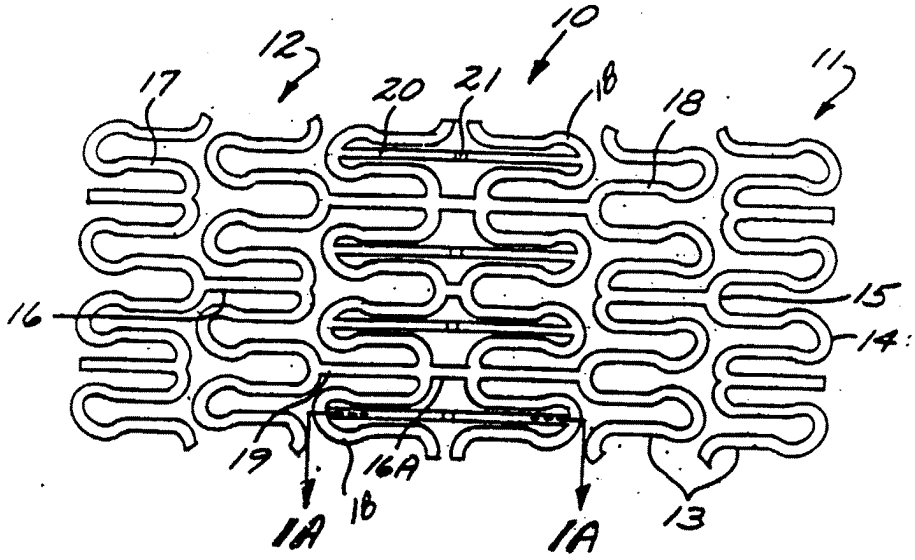


FIG. 1

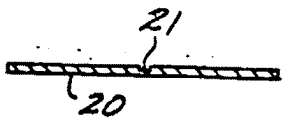


FIG. 1A

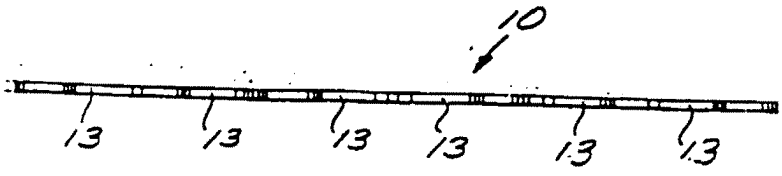


FIG. 1B

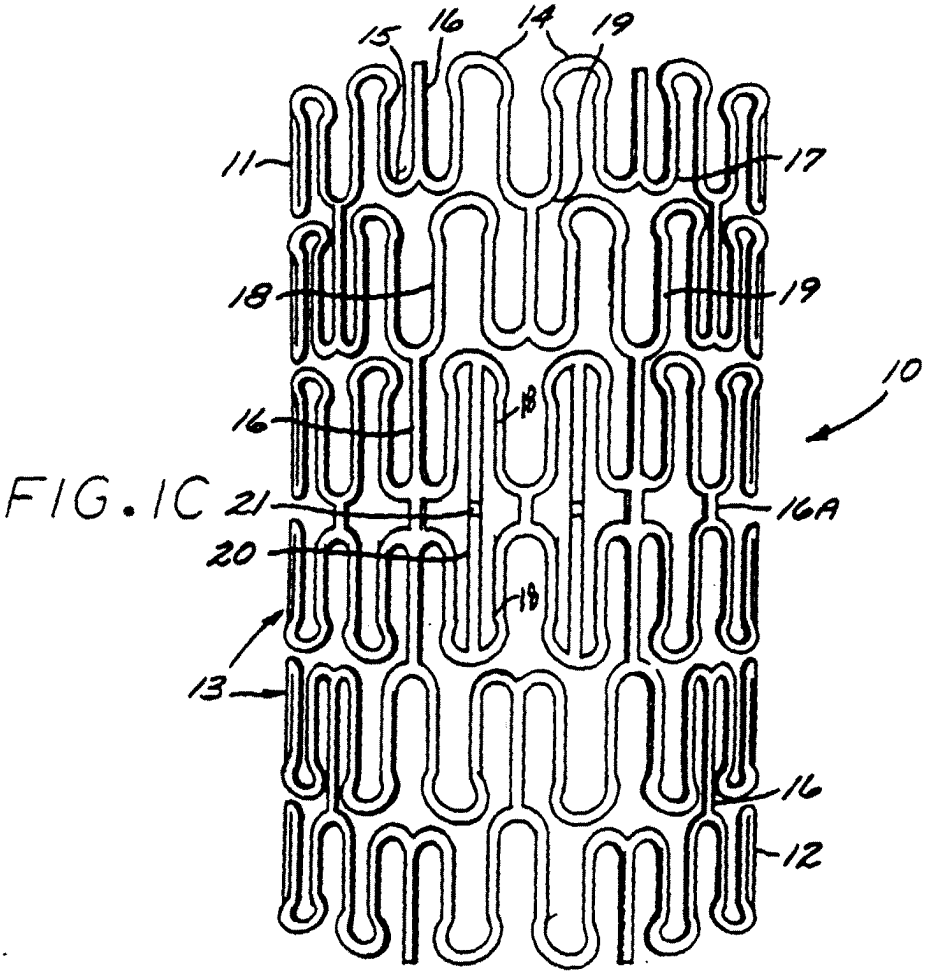


FIG. 1C

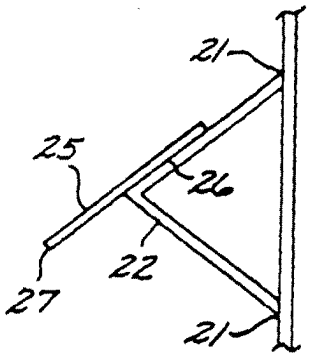


FIG. 2G

FIG.2

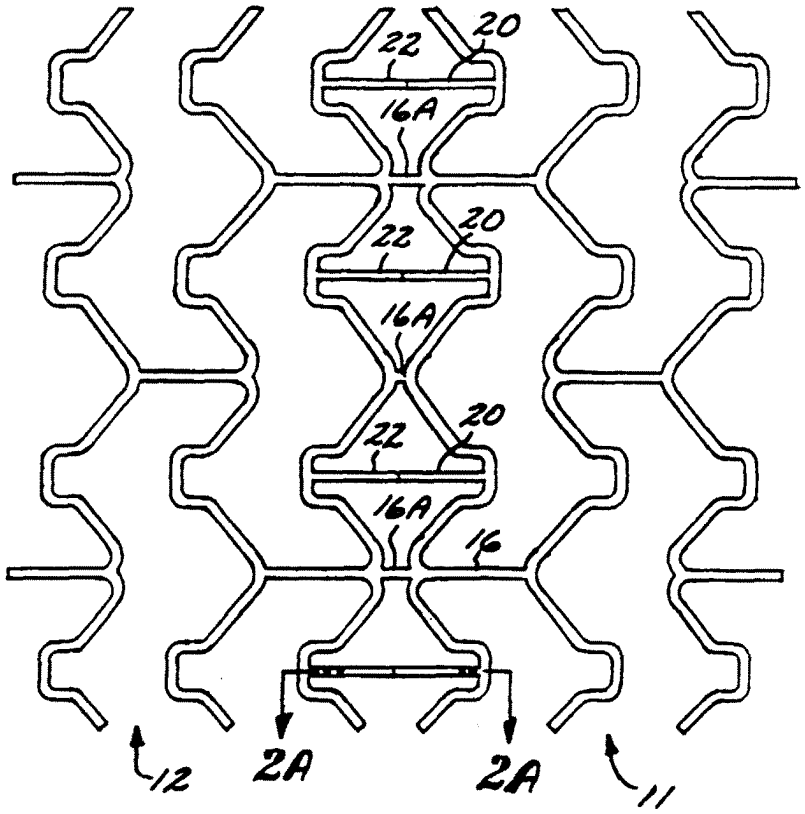


FIG.2A

FIG.2B

FIG. 2C

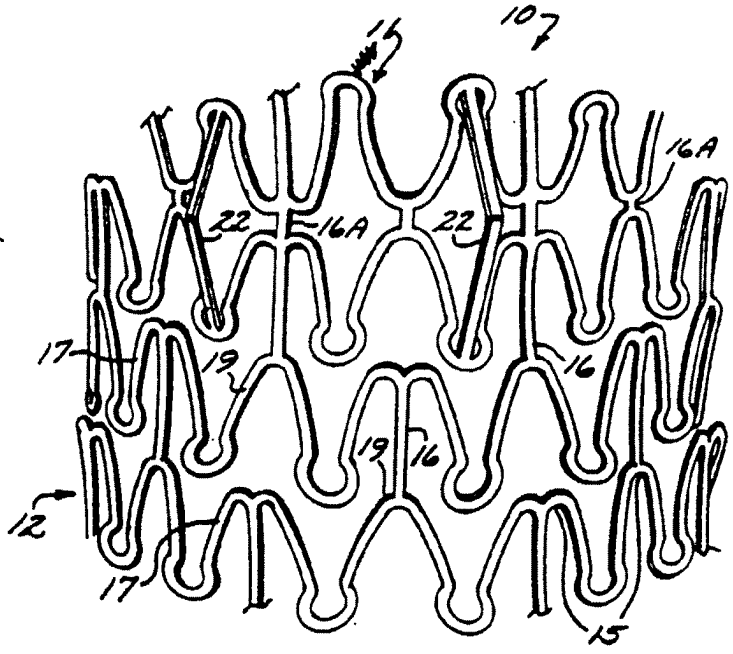


FIG. 2D

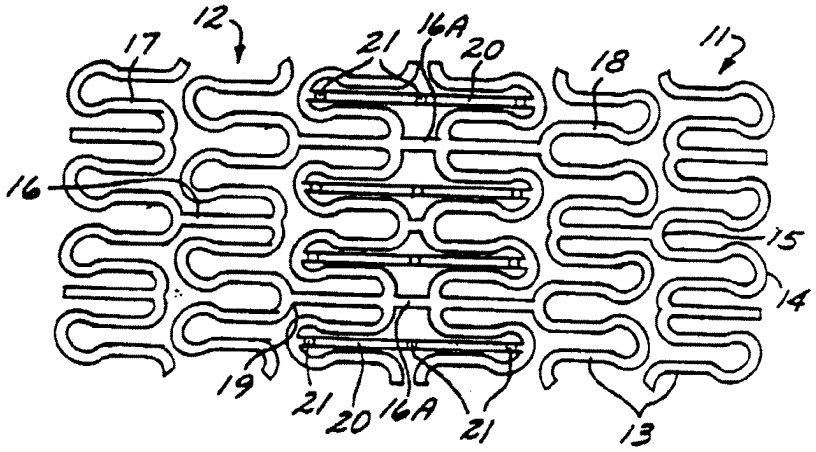
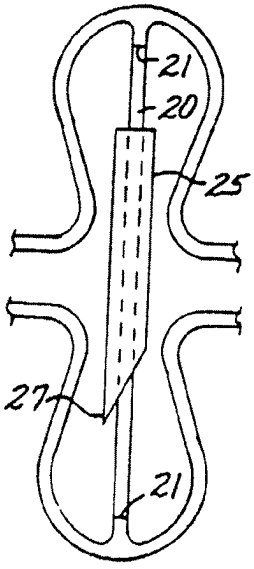


FIG. 2E



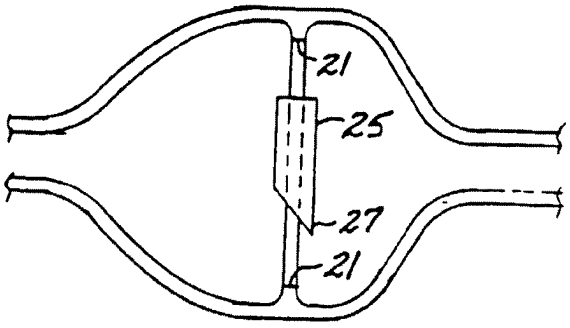


FIG. 2F

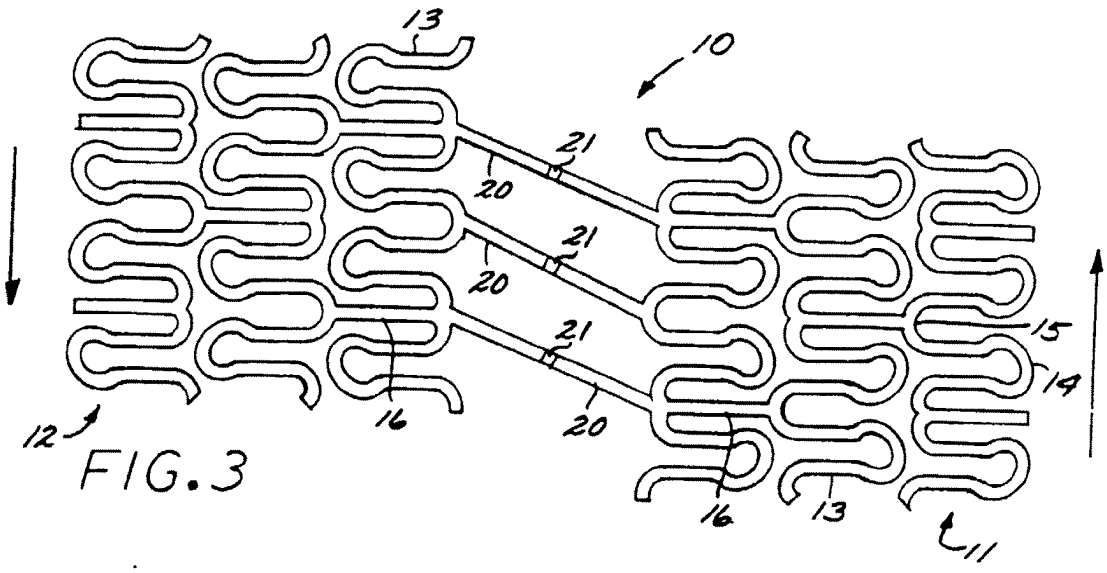


FIG.3

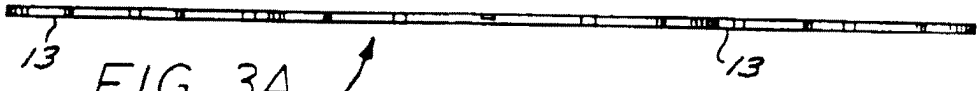


FIG.3A

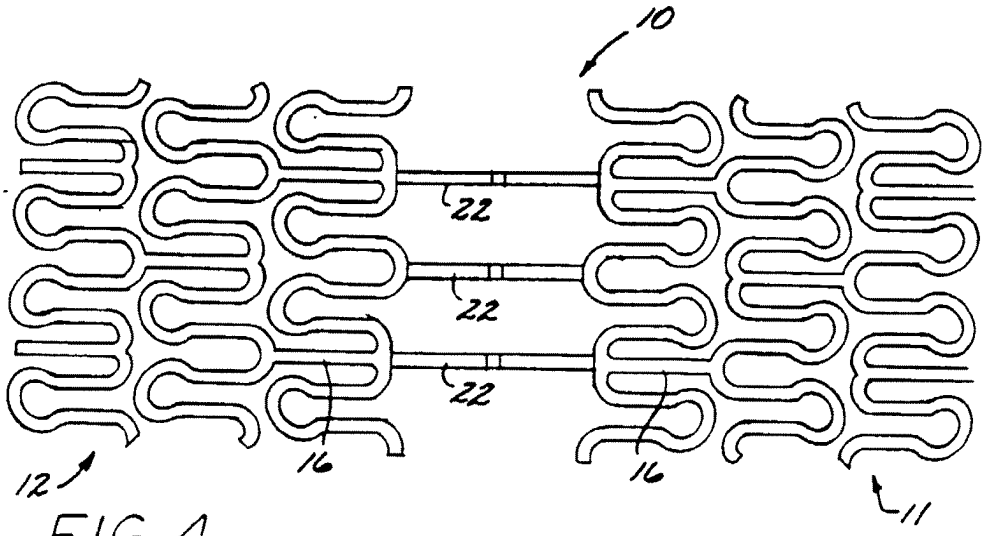


FIG.4

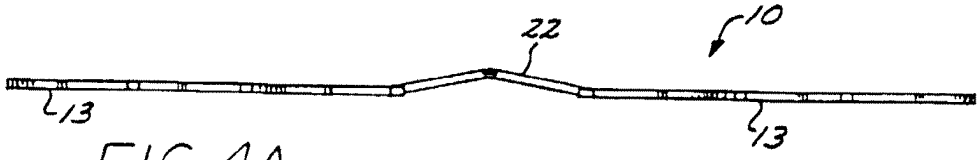


FIG.4A

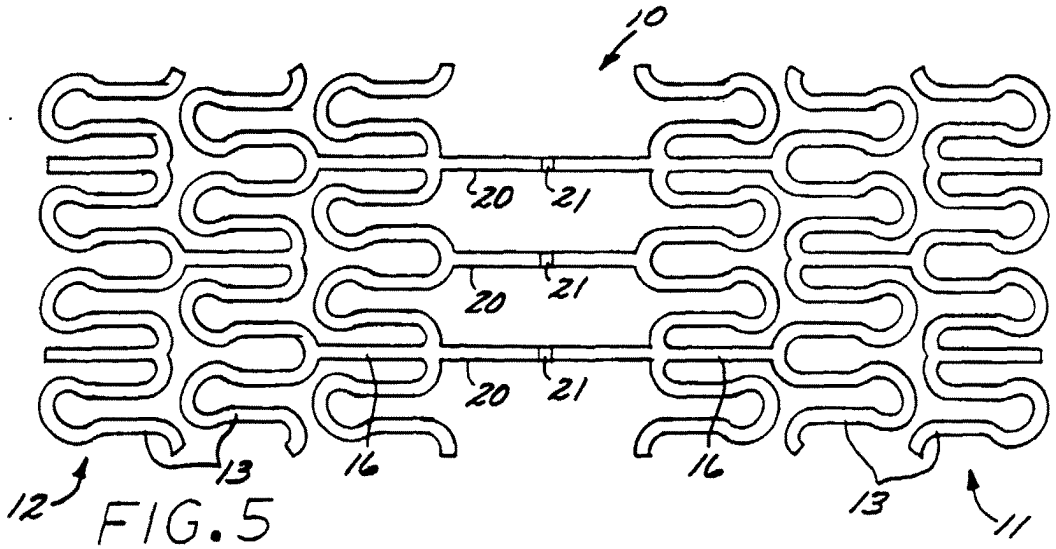


FIG.5

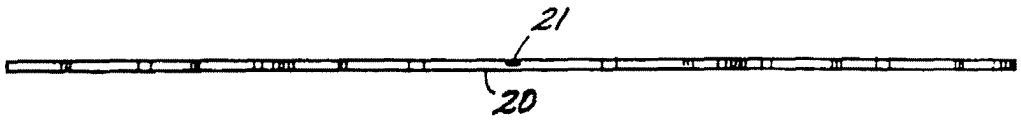


FIG.5A

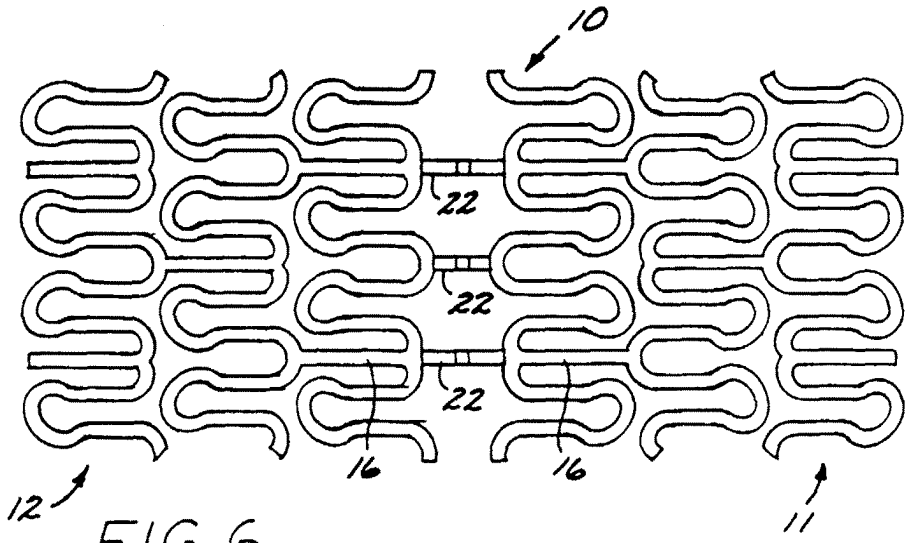


FIG.6

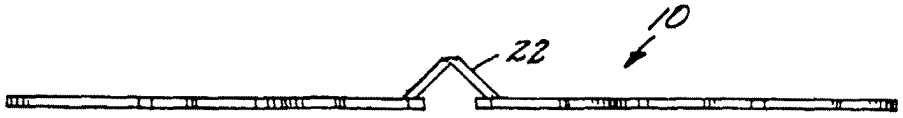


FIG.6A

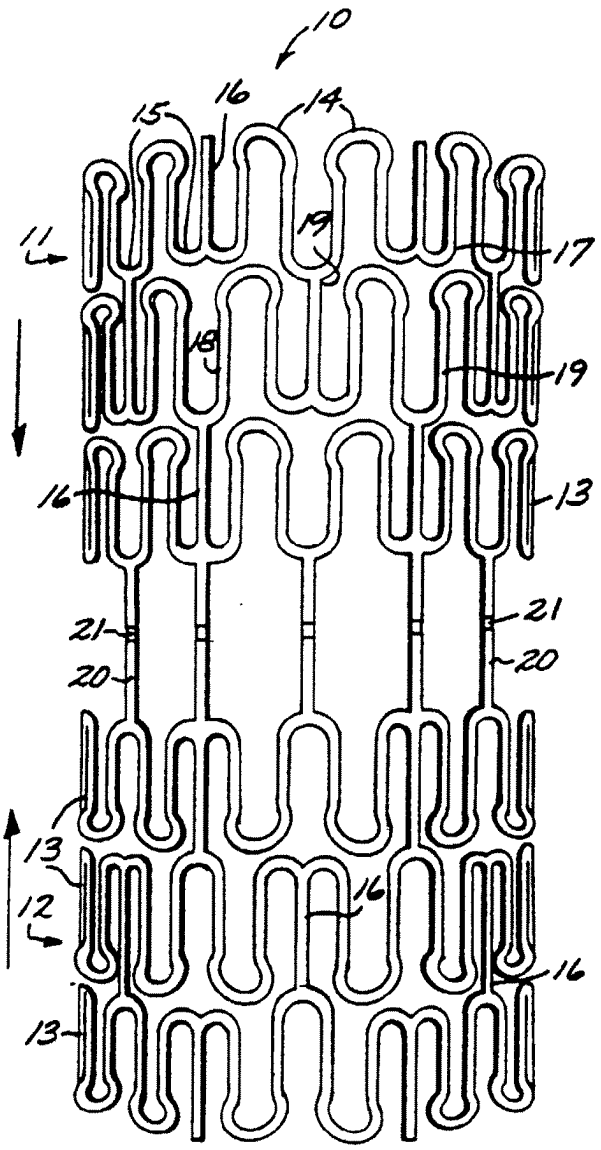

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FIG.6B

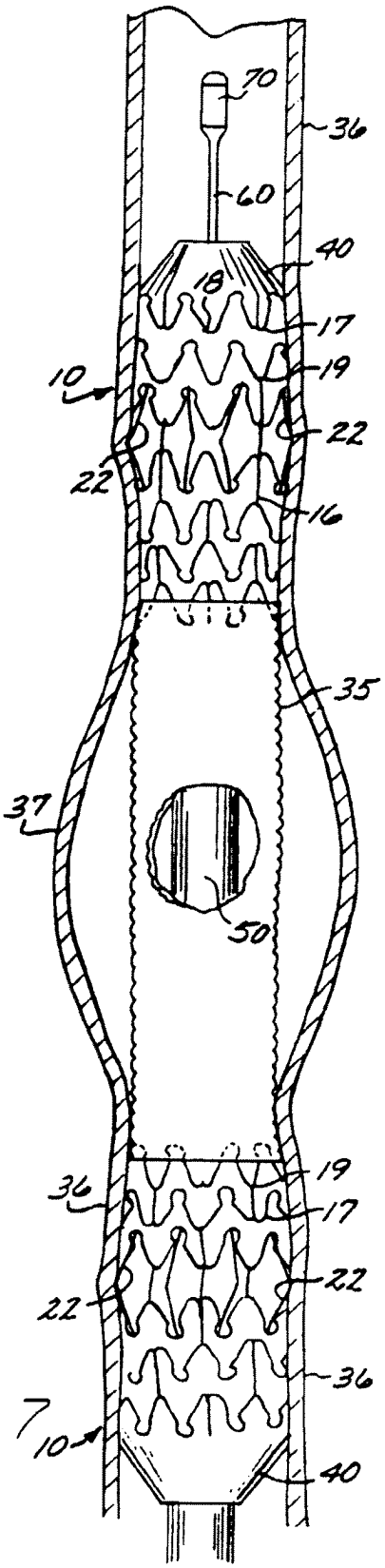
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FIG.7